Kintor Pharma

Developing Novel Drugs and Commercialization Platform

Confidential

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Major Accomplishments Since the Beginning of 2021

9 IND applications in China and US

- Proxalutamide for COVID-19 (3)
- Pyrilutamide for AGA (1)
- ALK-1+PD-1 for HCC(1)
- ALK-1+PD-L1/CTLA4 for multiple solid tumors(1)
- AR-PROTAC compound for AGA and acne (2)
- PD-L1/TGF-β antibody IND accepted (1)

3 registered phase III MRCTs for COVID-19 of proxalutamide

- Phase III MRCT for outpatients (US & Intl)
- Phase III MRCT for inpatients (US, China & Intl)
- Phase III MRCT for outpatients (China, Brazil & Intl)

1 emergency use authorization

- First EUA for hospitalized patients in Paraguay

TESÃI HA TEKO PORÃVE Motenondeha
Ministerio de SALUD PÚBLICA Y BIENESTAR SOCIAL

3 partnerships on commercialization of proxalutamide (COVID-19)

- With Fosun Pharma in India and 28 African countries
- With Etana in Indonesia
- With Visum regarding production capacity expansion of proxalutamide

1 clinical trial met primary endpoint

- KX-826's phase II trial for male AGA adults met primary endpoints in China
- The primary endpoint was the change from baseline in non-vellus TAHC at week 24 in comparison with placebo
- The majority of AEs were mild and no SAE occurred
- 5mg (0.5%) will be used in phase III trial in China

Capital Market

Inclusion in Hang Seng Composite Index

- Announced by Hang Seng Indexes Company on Aug 20
- Effective date is Sep 6

First placing after IPO

- Issued 18.2 million shares, which was 4.7% of total shares after placing
- Net proceeds was HKD1.16 billion (USD 150 million)

Staff

New hiring of talents

- New hired core management: Dr. Qun LU (CTO) responsible for CMC, and Dr. Jiawen HAN (BD VP) responsible for BD
- Besides, we have hired talents in clinical medicine/operations, project management and manufacturing for enriched pipeline and commercialization

Increase in staff

- Number of staff was increased to 272 as of June 30 from 202 in the beginning of 2021, with more than 50% in clinical and R&D function

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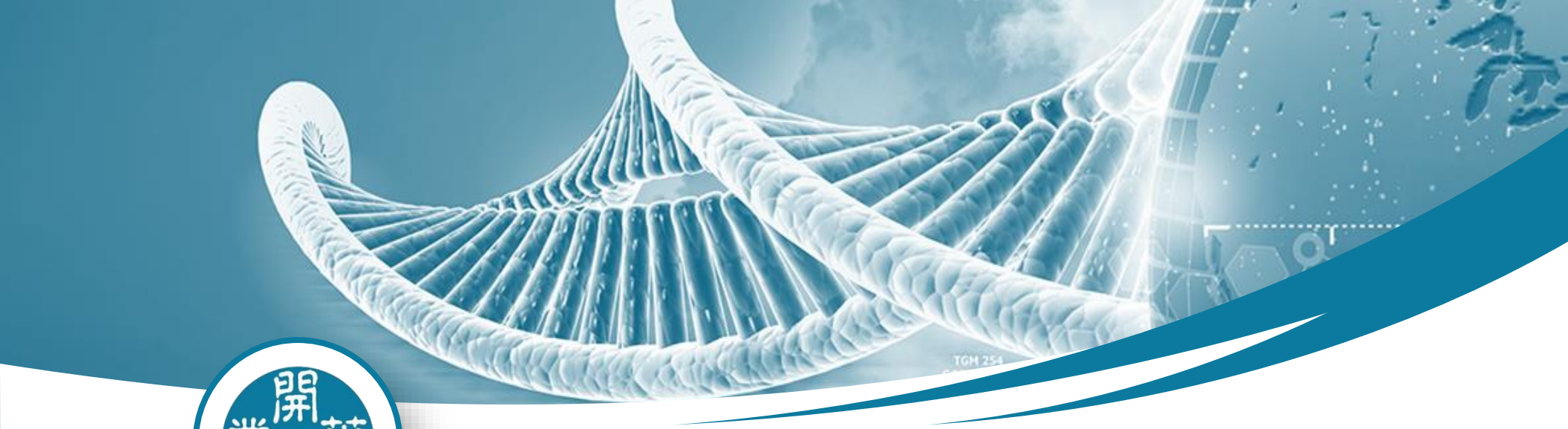


Section 1

Company Overview

Kintor at a Glance

2009

Established as Suzhou Kintor by Dr. Tong and Dr. Guo

Oncology & AR-Focused[1]

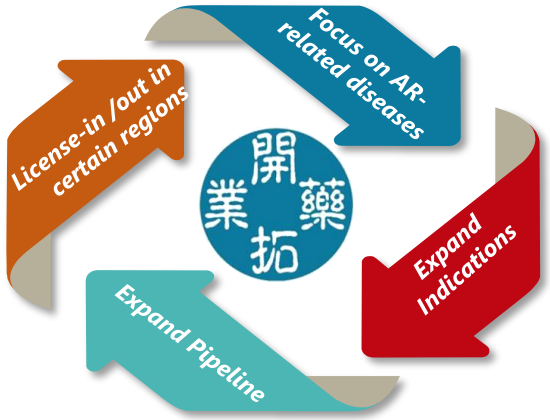
Focused on oncology AR-related diseases with substantial unmet medical needs

7+N Pipeline

Small molecule & biological drugs: 7 potential first/best-in-class in clinical, N in pre-clinical

Indications

COVID-19, fastest growing cancers (prostate, breast & liver) globally, and other AR-related indications like AGA[2] and acne vulgaris



Geographic Expansion

Potentially leveraging our global relationships to license-out select products for rapid global expansion in the future

Proxalutamide

Our lead product, indications in COVID-19, prostate cancer, and breast cancer. NDA filing in 2021

Pyrilutamide

Indications in androgenetic alopecia and acne vulgaris, ph II trial in China for AGA met primary endpoints

ALK-1 antibody

A new anti-angiogenesis inhibitor, positive data of HCC phase II trial in Taiwan, to commence trials in China and US

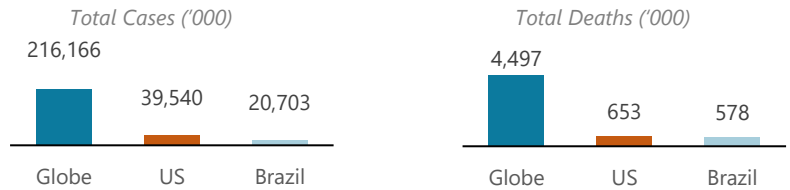
Note:
1 AR refers to androgen receptor 2. AGA:androgenetic alopecia

Our Mission

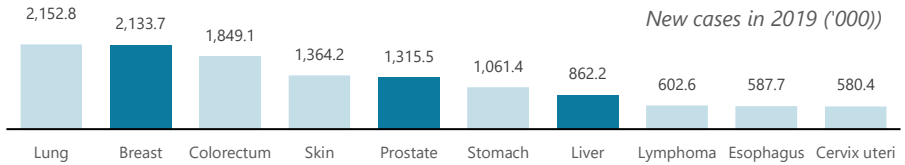
Our mission

*Focus on developing potential **"best-in-class"** and **"first-in-class" novel drugs** and commercialisation platform with the goal of becoming **a leading innovator** of drugs*

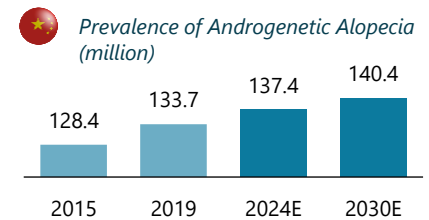
***COVID-19:** The pandemic spread and the total cases and deaths keep increasing (Dated Aug 27, 2021)*

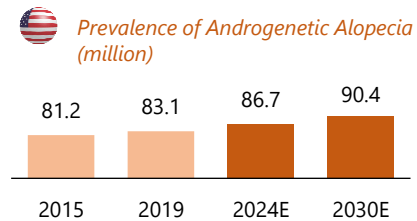


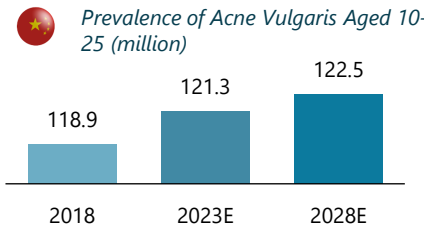
***Cancer:** Prostate cancer, breast cancer and liver cancer contributed to c.34% among Top 10 new cancer cases in 2019*

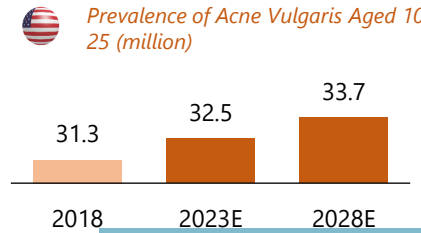


***Other AR-related diseases:** including androgenetic alopecia and acne vulgaris*



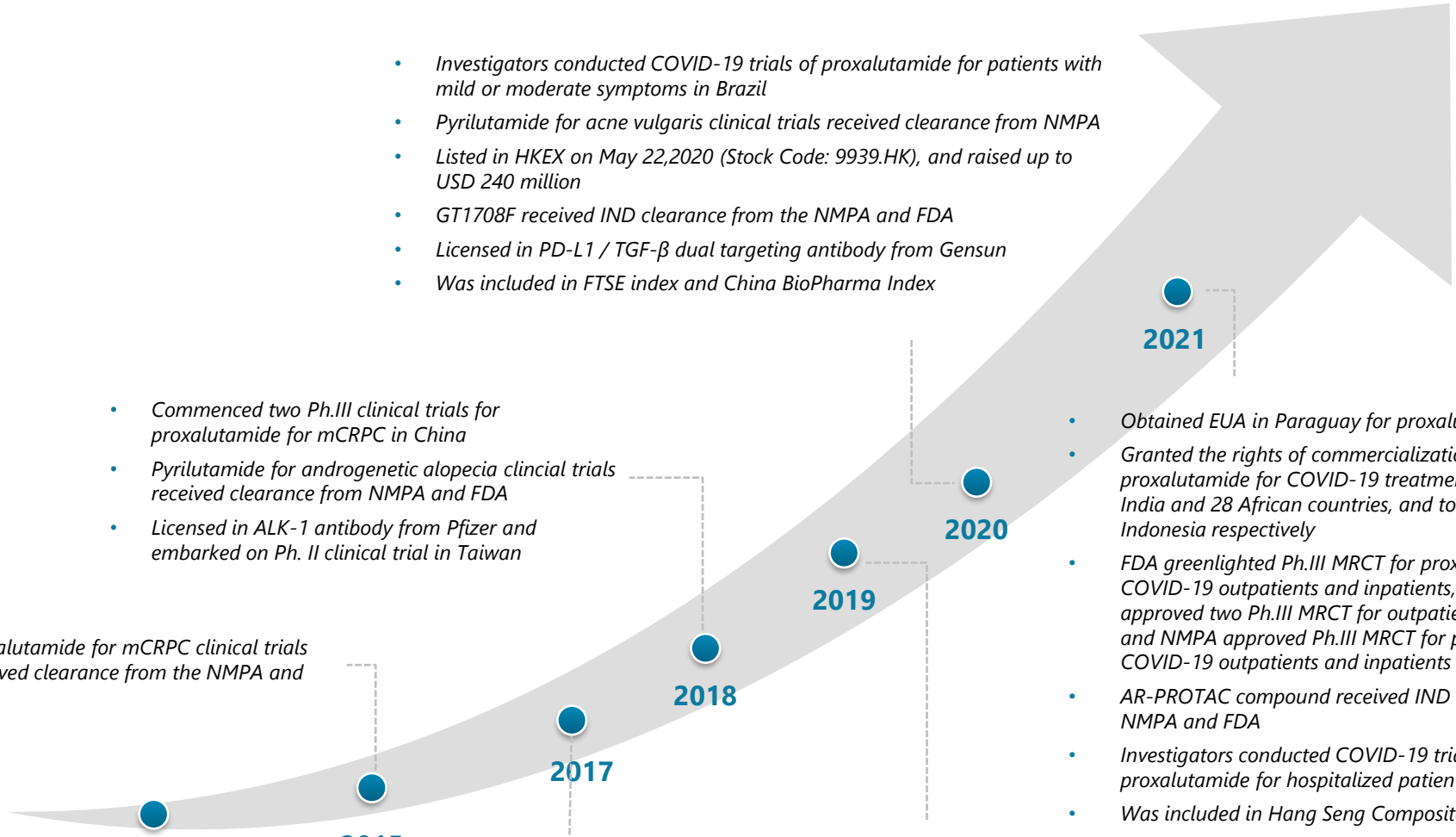






Source: Frost & Sullivan, Worldometer's COVID-19 data

Corporate Milestones



2009
- *Was established in Suzhou, China*

2015
- *Proxalutamide for mCRPC clinical trials received clearance from the NMPA and FDA*

2017
- *Proxalutamide for breast cancer clinical trials received clearance from the NMPA*

2018
- *Commenced two Ph.III clinical trials for proxalutamide for mCRPC in China*
- *Pyrilutamide for androgenetic alopecia clincial trials received clearance from NMPA and FDA*
- *Licensed in ALK-1 antibody from Pfizer and embarked on Ph. II clinical trial in Taiwan*

2019
- *Detorsertib received IND clearance from NMPA*

2020
- *Investigators conducted COVID-19 trials of proxalutamide for patients with mild or moderate symptoms in Brazil*
- *Pyrilutamide for acne vulgaris clinical trials received clearance from NMPA*
- *Listed in HKEX on May 22,2020 (Stock Code: 9939.HK), and raised up to USD 240 million*
- *GT1708F received IND clearance from the NMPA and FDA*
- *Licensed in PD-L1 / TGF-β dual targeting antibody from Gensun*
- *Was included in FTSE index and China BioPharma Index*

2021
- *Obtained EUA in Paraguay for proxalutamide*
- *Granted the rights of commercialization of proxalutamide for COVID-19 treatment to Fosun in India and 28 African countries, and to Etana in Indonesia respectively*
- *FDA greenlighted Ph.III MRCT for proxalutamide in COVID-19 outpatients and inpatients, ANVISA approved two Ph.III MRCT for outpatients in Brazil, and NMPA approved Ph.III MRCT for proxalutamide in COVID-19 outpatients and inpatients*
- *AR-PROTAC compound received IND clearance from NMPA and FDA*
- *Investigators conducted COVID-19 trials of proxalutamide for hospitalized patients in Brazil*
- *Was included in Hang Seng Composite Index*

mCRPC = metastatic castration-resistant prostate cancer, NMPA = National Medical Products Administration, FDA = U.S. Food and Drug Administration, EUA = Emergency Use Authorization, PROTAC = proteolysis targeting chimera, MRCT = Multi Regional Clinical Trials, ANVISA = Brazilian Health Regulatory Agency

Products Pipeline

	Drug Candidate	Target / Mechanism	Indication	Country/ Region	Pre-Clinical	IND Filing (Filed)|(Accepted)	Phase I	Phase II	Phase III	NDA
Clinical Stage Products	**Proxalutamide (GT0918)**	Second generation AR antagonist	COVID-19 (Outpatients)	US & Intl		*Completed first patient enrolment on Apr 24, 2021*				
			COVID-19 (Inpatients)	US, China & Intl		*FDA greenlighted to conduct on May 17, 2021*				
			COVID-19 (Outpatients)	China, Brazil & Intl		*IND was approved by ANVISA on Jun 11, 2021*				
			mCRPC	China		*Expected to submit NDA in 2021*				
			Combination therapy with Abiraterone for mCRPC	China		*Expected to complete patients enrolment in 2021*				
			mCRPC	US		*Expected to complete phase II in 2021*				
			Metastatic breast cancer	China						
			Combination therapy with Exemestane, Letrozole and Fulvestrant for metastatic breast cancer	China		*Completed patients enrolment on Aug 25, 2021*				
	Pyrilutamide (KX-826)	AR antagonist (for external use)	Androgenetic alopecia	China		*Announced primary endpoint was met on Sep 8, 2021*				
			Androgenetic alopecia	US		*FDA greenlighted to conduct on Jul 7, 2021*				
			Acne vulgaris	China		*Completed FPI on Apr 16, 2021*				
			Acne vulgaris	US						
	ALK-1 (GT90001)	Angiogenesis inhibitor	Combination therapy with a PD-1 for metastatic HCC (2L)	Taiwan		*Interim data was released at ASCO GI in Jan 2021*				
			Combination therapy with a PD-1 for metastatic HCC (2L)	US & Intl		*IND was approved on Feb 18, 2021*				
			HCC (1st-line combination therapy)	China		*Preparing for IND*				
			Combination therapy with KN046 (PD-L1/CTLA-4) for HCC, GC, GEJ adenocarcinoma, UC, ESCC	Taiwan						康宁杰瑞 ALPHAMAB ONCOLOGY
	Detorsertib (GT0486)	mTOR kinase inhibitor	Metastatic solid tumours	China						
	GT1708F	Hedgehog/ SMO inhibitor	Leukaemia	China						
			Basal-cell carcinoma	US						
	GT20029	AR-PROTAC compound	AGA and acne vulgaris	China		*First batch of patients were dosed on Jul 28, 2021*				
			AGA and acne vulgaris	US		*IND clearance granted on Jul 8, 2021*				
	GT90008	PD-L1 / TGF-β dual targeting antibody	Multiple types of solid tumours	China		*IND was accepted on Aug 16, 2021*				
Pre-Clinical		Other AR-PROTAC compounds	Multiple indications							
		c-Myc inhibitor	Blood cancer							
		ALK-1/VEGF bispecific antibody	Solid tumours							

Trials initiated by Kintor Trials initiated by Kintor and partners

HCC = hepatocellular carcinoma, GC = gastric carcinoma, GEJ = gastroesophageal junction, UC= urothelial carcinoma, ESCC = esophageal squamous cell carcinoma,

Achievements and Near-Term Outlook of Proxalutamide in COVID-19

Emergency Use Authorization

- *First EUA for hospitalized patients in Paraguay*
- *Announced on Jul 16, 2021*

Phase III MRCT for male and female outpatients (US & Intl)

Countries and regions:

The United States, South America (including Brazil), EU, India, etc.

FDA greenlighted to conduct on Mar 4, 2021 → *Commenced patients enrolment on April 24, 2021* → *IND was approved by ANVISA on Jul 19, 2021 in Brazil*

Phase III MRCT for male and female inpatients (US, China & Intl)

Countries and regions:

The United States, China, South America (including Brazil), EU, India, etc.

FDA greenlighted to conduct on May 17, 2021 → *IND was approved by NMPA on Sep 1, 2021 in China*

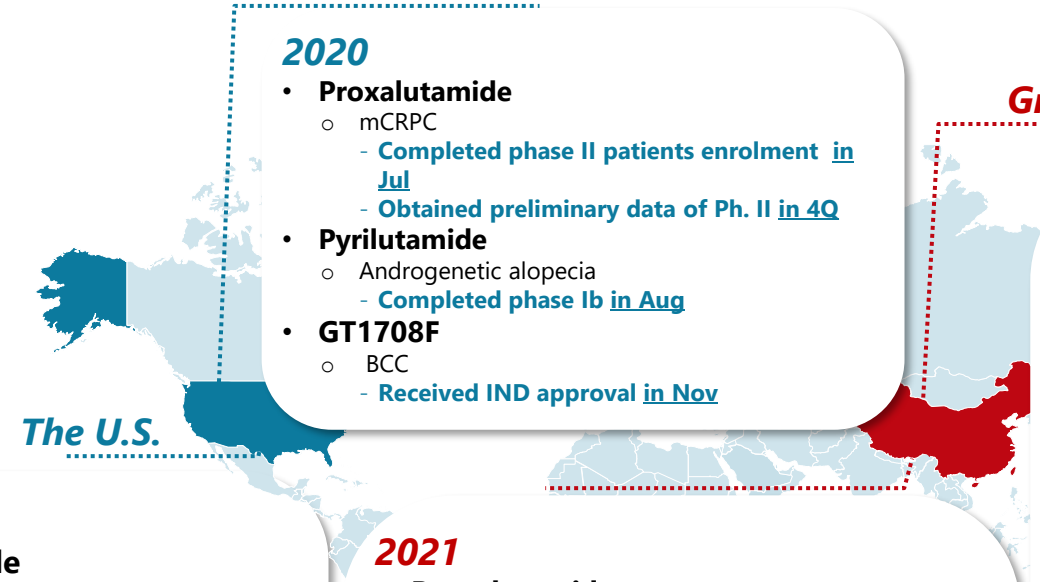
Phase III MRCT for male outpatients (China, Brazil & Intl)

Countries and regions:

China, South America (including Brazil), China, SEA (including Philippines), EU, etc.

IND was approved by ANVISA on Jun 11, 2021 in Brazil → *IND approved in Philippines, Malaysia, etc. since Jun* → *Commenced patients enrolment in Brazil* → *IND was approved by NMPA on Sep 1, 2021 in China*

Achievements and Near-Term Outlook in other R&D



The U.S.

2020

- **Proxalutamide**
  - mCRPC
    - **Completed phase II patients enrolment in Jul**
    - **Obtained preliminary data of Ph. II in 4Q**
- **Pyrilutamide**
  - Androgenetic alopecia
    - **Completed phase Ib in Aug**
- **GT1708F**
  - BCC
    - **Received IND approval in Nov**

2021

- **Proxalutamide**
  - mCRPC
    - **Publish result of Ph. II at ASCO GU in Feb**
    - Complete Phase II
- **Pyrilutamide**
  - AGA
    - **Received greenlight of Phase II in Jul**
- **ALK-1**
  - HCC
    - **IND approved in Feb**
- **AR-PROTAC compound**
  - AGA and acne vulgaris
    - **IND clearance was granted in Jul**

2021

- **Proxalutamide**
  - mCRPC
    - **Published result of Ph. II at ASCO GU in Feb**
- **Pyrilutamide**
  - AGA
    - **Completed patient dosing in Jun**
    - **Issued data of Ph. II in Sep**
  - Acne Vulgaris
    - **Completed Ph. I/II first patient dosing in Apr**
- **ALK-1**
  - HCC
    - **Released interim data of Taiwan Ph. II trial at ASCO GI in Jan**
- **AR-PROTAC compound**
  - AGA and acne vulgaris
    - **IND was approved in Apr**
    - **First batch of patients were dosed in Jul**
- **PD-L1 / TGF-β dual targeting antibody**
  - Multiple types of solid tumours
    - **IND was accepted in Aug**

Greater China

2020

- **Proxalutamide**
  - mCRPC
    - **Completed phase III patients enrolment in Aug**
- **Pyrilutamide**
  - Acne Vulgaris
    - **Received IND approval in Sep**
  - AGA
    - **Complete patients enrolment in Dec**
- **ALK-1**
  - HCC and other indications
    - **Conducted the combination therapy with PD-L1 / CTLA-4 bispecific of Alphamab in Jul, and commence global trials successively**
- **PD-L1 / TGF-β dual targeting antibody**
  - Multiple types of solid tumours
    - **Obtained an exclusive right from Gensun in Aug to promote the clinical development and commercialization in Greater China, and also obtained the right of first refusal outside Greater China**
- **GT1708F**
  - Leukaemia
    - **Received IND approval in Feb**

Growing from Small Molecules to Biologics: Co-Development + License-In + Innovation

Cooperated with outstanding domestic and foreign companies in R&D and manufacturing of biologics

康宁杰瑞 ALPHAMAB ONCOLOGY

Develop the combination therapy of ALK-1 monoclonal antibody

In July 2020, entered into a partnership agreement with Alphamab to jointly develop the combination therapy of ALK-1 monoclonal antibody GT90001 and PD-L1 / CTLA-4 bispecific antibody KN046 in hepatocellular carcinoma (HCC).

Gensun

Introduce dual-targeting antibody for layout of biologics in dual/triple-targeting

In Aug 2020, obtained an exclusive right from Gensun to promote the clinical development and commercialization in Greater China, and also obtained the right of first refusal outside Greater China.

MabPlex 迈百瑞

All-round cooperation in the R&D and manufacturing of biologics

In Sep 2020, entered into a strategic cooperation agreement with MabPlex, and the CMC work for GT90008 (PD-L1/TGF-β dual targeting antibody) was officially initiated.

Make A Breakthrough in Biological Compounds and Speed up Combo Therapies for A Variety of Tumours

Candidates	Mono/combo therapies	Indications
Combo therapies with other biological compounds		
☑ ***ALK-1***	*Combination therapy with **PD-1 or PD-L1** antibodies*	➢ *HCC*
	*Combination therapy with **PD-L1/TGF-β** dual targeting antibodies*	➢ *Multiple types of solid tumours*
	*Combination therapy with **PD-L1/CTLA-4** bispecific antibodies*	➢ *HCC and multiple types of solid tumours*
	Combination therapy with other monoclonal/bispecific antibodies	➢ *Multiple types of solid tumours*
☑ ***PD-L1/TGF-β dual targeting antibody***	*Monotherapy*	➢ *Multiple types of solid tumours*
	*Combination therapy with **ALK-1***	➢ *Multiple types of solid tumours*
	Combination therapy with other monoclonal/bispecific antibodies	➢ *Multiple types of solid tumours*
Combo therapies with small molecules		
☑ ***ALK-1 -or- PD-L1/TGF-β dual targeting antibody***	*Combination therapy with **proxalutamide** (AR antagonist)*	➢ *mCRPC/mBC*
	*Combination therapy with **Detorsertib** (mTOR inhibitor)*	➢ *Multiple types of solid tumours*

GMP Facilities and Commercialization

MANUFACTURING AND R&D BASE

- ***c. 20,000 m2*** *factory in Suzhou*
- ***Put into operation*** *at the end of Aug 2020*
- *Received production permit in 23 Nov 2020, and will obtain China GMP certification, as well as* ***FDA GMP and EU GMP*** *subsequently*
- *To meet the commercialization needs of proxalutamide (expect* ***50 million tablets*** *per month capacity in Q4) , and clinical needs of pyrilutamide*

STRATEGIC COOPERATION AGREEMENT

PT Etana Biotechnologies

In Aug 2021, signed the licensing agreement with Etana on the commercialization of proxalutamide for the treatment of COVID-19 in Indonesia. Kintor will receive upfront and milestone payments and economic benefit relating to the sales

Fosun Pharma Development

In Jul 2021, signed licensing agreement with Fosun on the commercialisation of proxalutamide for COVID-19 in India and 28 African countries. Kintor will receive upfront and milestone payments up to RMB560 million and royalty not less than 50% of total operating profit

Visum Pharma

In Apr 2021, signed the strategic cooperation agreement with Visum which has strength in production and was certified by US FDA, on expanding the supply capacity of proxalutamide

JD Pharmacy

In Jun 2020, signed a strategic cooperation framework agreement with JD Pharmacy in the marketing and sales of pyrilutamide

Sinopharm

In Mar 2020, signed the strategic cooperation agreement with Sinopharm in the market development of pyrilutamide

Section 2

Investment Highlights

Investment Highlights

01 

Risk-balanced and **diversified** pipeline of drug candidates targeting major cancer types and other AR-related indications with **substantial market potential**

02 

Positive clinical results of proxalutamide COVID-19 trial demonstrated that it's likely an effective drug for the treatment of COVID-19 among current therapies

03 

Potential best-in-class AR antagonist for mCRPC, forming the backbone of potential combination therapies for AR-related cancers

04 

Pyrilutamide is an AR antagonist developed as a novel **topical drug** for the treatment of androgenic alopecia and acne vulgaris

05 

ALK-1 is a potential **first-in-class** fully humanised IgG2 neutralising monoclonal antibody that can both inhibit the growth of tumour vessels / reduce their blood flow and vascularisation

06 

Other novel drugs indications in **multiple solid tumors**

07 

Integrated R&D platform coupled **with seasoned scientists** enabling us to maintain quality and efficiency over our entire drug development process

1 Risk-balanced Pipeline of Potential First- and Best-In-Class Products...

Best-in-Class

Seek incremental yet significant improvements to existing treatment options

First-in-Class

Innovative drugs that seek to substantially expand the addressable market for the target indications

Proxalutimide
*Potential **best-in-class** drug based on the well-researched AR mechanism and proven target*

Pyrilutamide
*Potential **first-in-class** drug based on AR mechanism target to redefine androgenetic alopecia market*

ALK-1
*Potential **first-in-class** antibody to be used in combination with PD-1 for solid tumors*

Detorsertib
*Potential **first-in-class** mTORC1 and mTORC2 dual inhibitor*

GT1708F
*Potential **best-in-class** Hedgehog signaling pathway SMO inhibitor*

GT20029
*AR-PROTAC compound developed by using our **in-house** Protac platform*

GT90008
*With a high activity in **inhibiting both PD-L1 and TGF-β***

6 clinical-stage candidates

10+ ongoing clinical studies

Global clinical program
in China(including Taiwan), U.S., and Brazil

Fully in-house
developed novel compounds

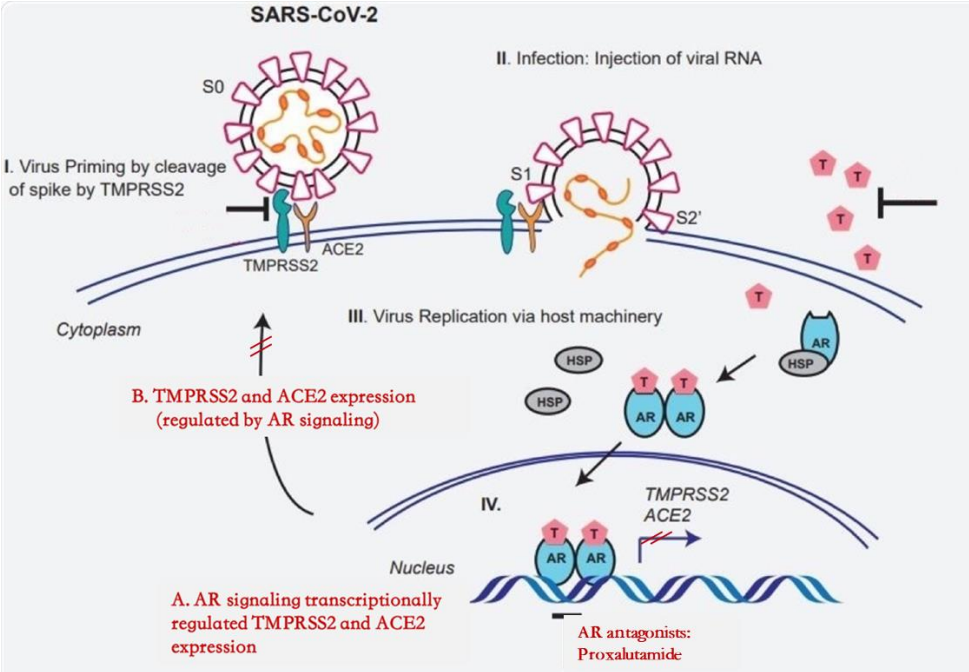
***Proxalutamide** - Patent expiration date is Mar 8, 2032; **Pyrilutamide** - Patent expiration date is Sep 8, 2030*

Kintor has designed a two-pronged strategy for its Risk-balanced and Diversified product pipeline

Source: Company Prospectus, Frost & Sullivan analysis

AR Signaling Regulates ACE2/TMPRSS2 Mediated SARS-CoV-2 Infection

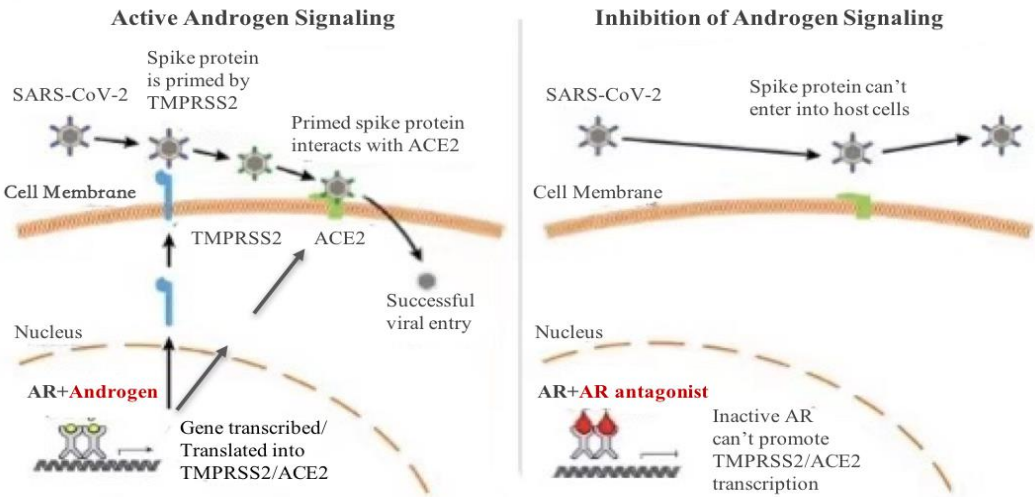
2



SARS-CoV-2 entry into host cells requires two host cell surface proteins: ACE2 and TMPRSS2.

- *The spike protein need to be primed by TMPRSS2 before it could interact with ACE2 to get the RNA of the virus entered into host cells.*
- *The expression of TMPRSS2 and ACE2 are positively regulated by the AR signaling.*
- *Targeting AR-ACE2/TMPRSS2 signal axis could originally inhibit the entry of the virus into host cells by transcriptionally downregulating the expression of TMPRSS2 and ACE2, which has gradually been receiving growing attention as potential therapies for COVID-19.*

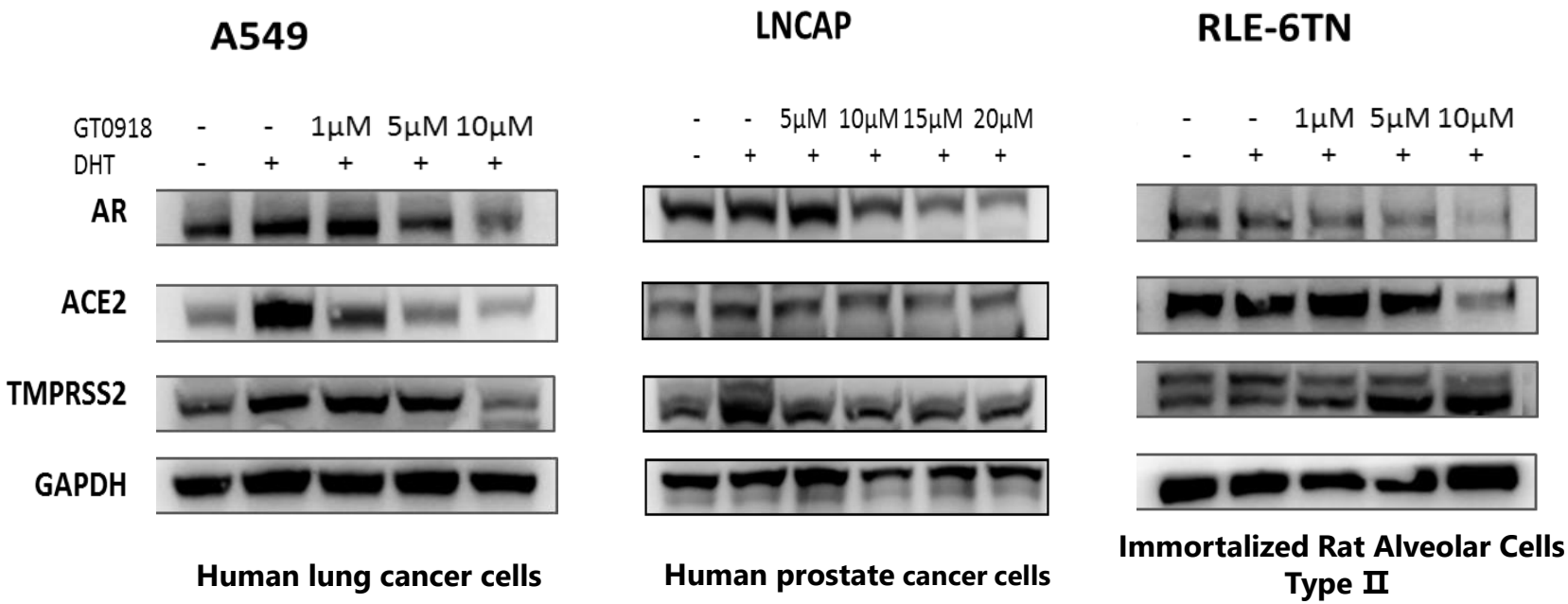
AR antagonists (like proxalutamide) inhibit SARS-CoV-2 entry into host cells by inhibiting the function of AR and downregulating the expression of ACE2 and TMPRSS2



Source: Qiao Y., et al, Proceedings of the National Academy of Sciences. 2021; Leach D. A., et al, Research Squae. r2021. .

MoA of Proxalutamide (1) : Downregulates AR, ACE2 and TMPRSS2 Expression

2



Proxalutamide inhibited ACE2 and TMPRSS2 protein expression in human lung and prostate cancer derived cells and normal lung epithelial cells, suggesting proxalutamide can ***block SARS-CoV-2 cellular entry into host cells****.*

Sources: 1. Wu, Siqi et al, SSRN Electronic Journal. doi:10.2139/ssrn.3580526. ISSN 1556-5068

2 MoA of Proxalutamide (2) : Inhibits SARS-CoV-2 Variant

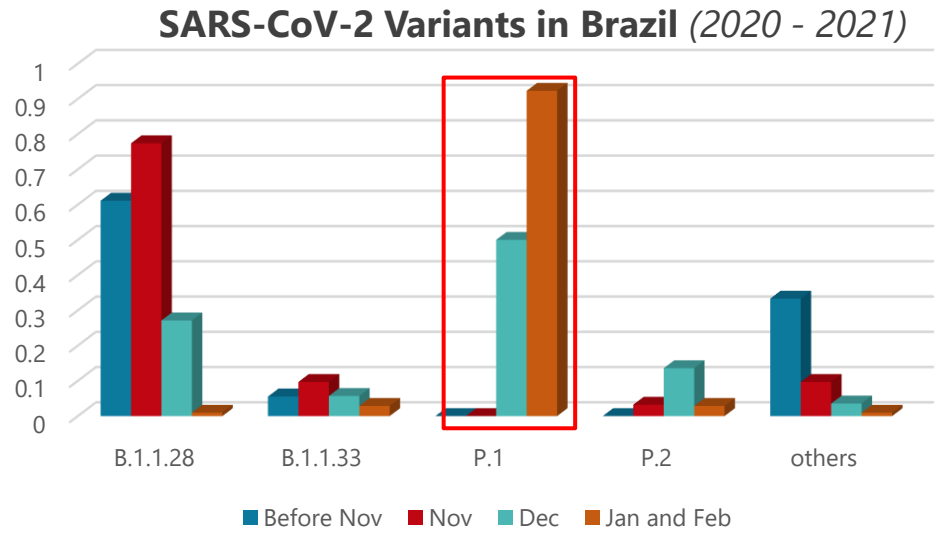
- *So far, the in vitro studies in the P3 laboratory have demonstrated that proxalutamide can effectively inhibit infections caused by the Alpha and Delta variants.*
- *The outcome of genome sequencing on COVID-19 inpatients in Brazil has shown that proxalutamide has effectively treated inpatients infected by Gamma variant.*
- *The SARS-CoV-2 Gamma (P.1) variant came to dominated in Brazil since 12/2020 and has spread to many countries out of Brazil.*

SARS-CoV-2 Variants in Brazil (No. (%))

Time Period	P.1	P.2	B.1.1.28	B.1.1.33
2021 Jan & Feb	**96 (92%)**	3 (3%)	1 (1%)	3 (3%)
2020 Dec	**70 (50%)**	19 (14%)	38 (27%)	8(6%)
2020 Nov	**0**	1 (3%)	24 (77%)	3(10%)
Before 2020 Nov	**0**	0	11 (61%)	1(6%)

SARS-CoV-2 Variants in Amazonas (No. (%))

Time Period	P.1	P.2	B.1.1.28	others
2021 Jan	**32 (91%)**	2 (6%)	0	1 (3%)
2020 Dec	**28 (51%)**	6 (11%)	17 (31%)	4 (7%)
2020 Nov	**0**	1 (4%)	19 (79%)	4 (17%)



Data resource: GISAID N = 293

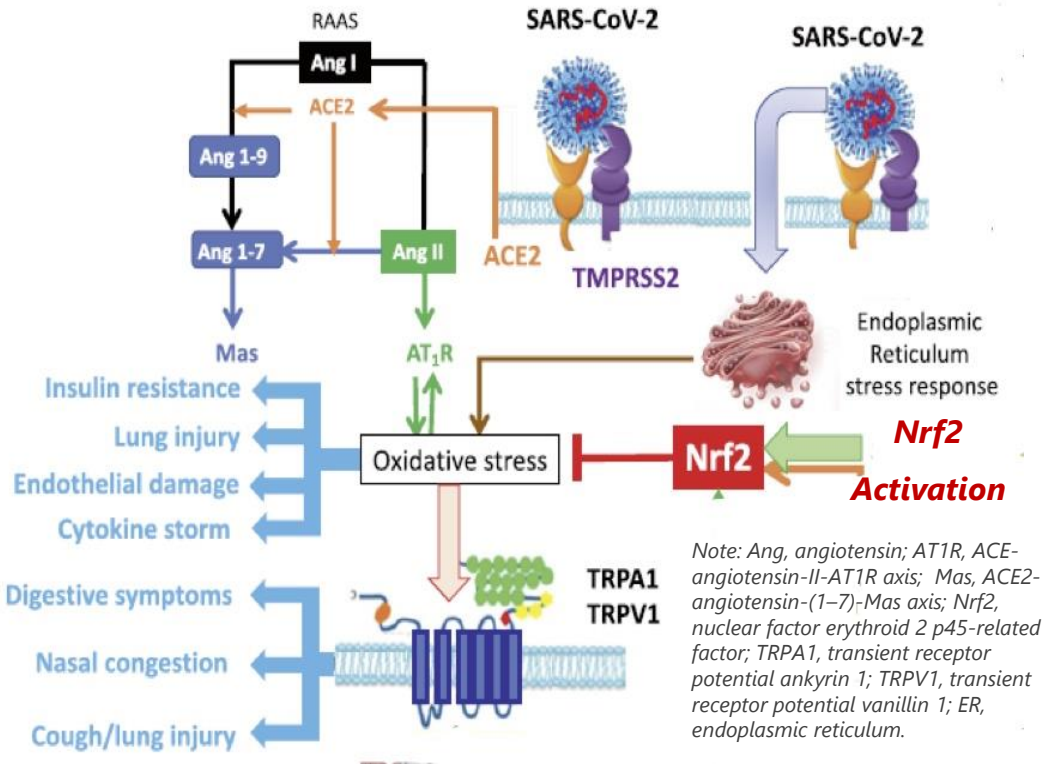
Figure 1. Municipalities of the Amazonas state with SARS-Cov-2 P.1 lineage samples sequenced in this study.

Update of the SARS-CoV-2 genomic surveillance in the amazonas state, Brazil, https:// virological.org.

MoA of Proxalutamide (3) : Upregulation of Nrf2 Signaling Inhibits the Overproduction of Proinflammatory Cytokines

2

Nrf2 Can Downregulate the Oxidative Stress from the AT1R Axis as Well as in the ER



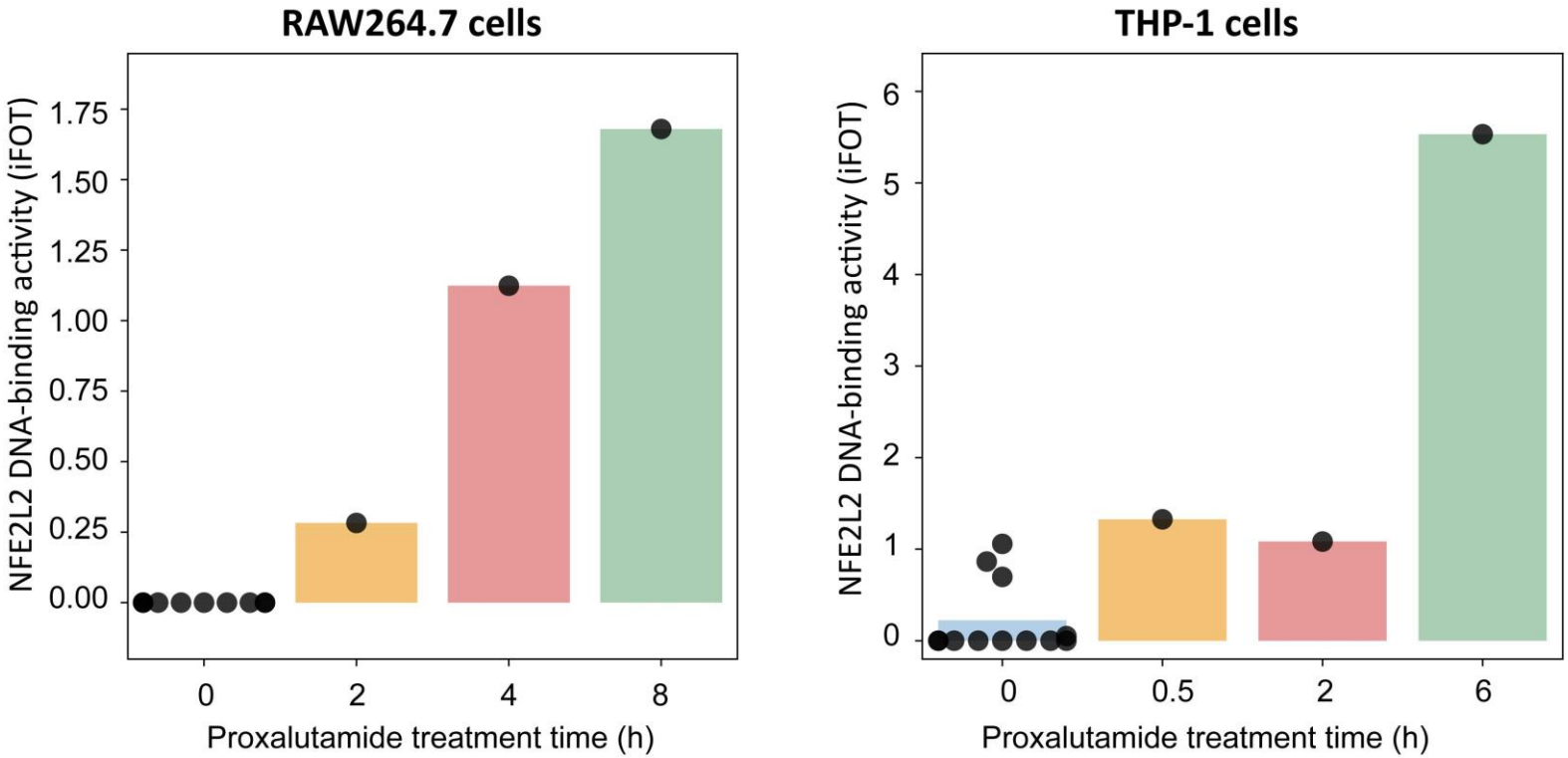
Note: Ang, angiotensin; AT1R, ACE-angiotensin-II-AT1R axis; Mas, ACE2-angiotensin-(1–7)-Mas axis; Nrf2, nuclear factor erythroid 2 p45-related factor; TRPA1, transient receptor potential ankyrin 1; TRPV1, transient receptor potential vanillin 1; ER, endoplasmic reticulum.

- *A common denominator in all conditions associated with COVID-19 appears to be the impaired redox homeostasis, responsible for the accumulation of reactive oxygen species (ROS).*
- *SARS-CoV-2 binds to ACE2, and ACE2 downregulation enhances the AT1R axis leading to oxidative stress generation.*
- *In particular, the upregulation of Nrf2 signaling inhibits the overproduction of **IL-6**, **proinflammatory cytokines**, and **chemokines**.*
- *It also limits the activation of nuclear factor-kappa b (NFκB) which is also involved in oxidative stress.*

Source: Bousquet et al. Int Arch Allergy Immunol. DOI: 10.1159/000513538.

MoA of Proxalutamide (3) : Increases Nrf2 Transcription Factor Response Element Binding Activity

2



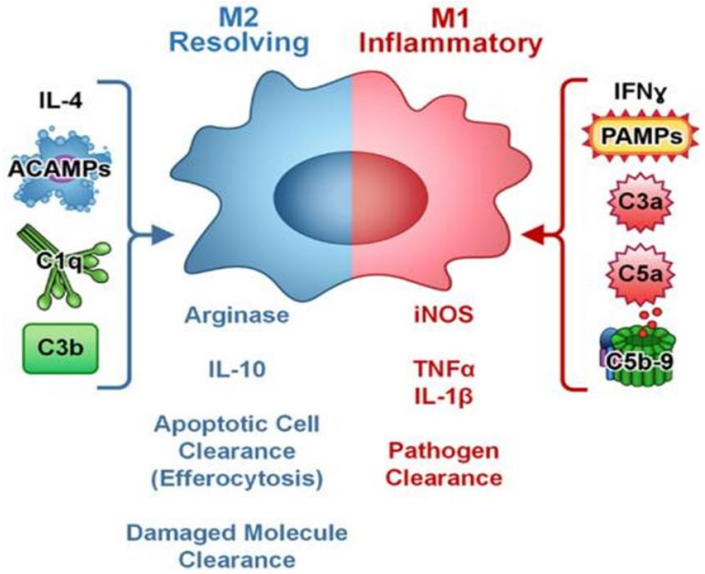
- *Proxalutlamide increased Nrf2 transcription factor response element binding activity in macrophage and monocyte cells*
- *Proxalutamide bound to the promoter region to activate transcriptional factor Nrf2, which is a major factor involved in down regulation of inflammation factors*

Source: Prof. Qin Jun from Beijing Proteome Research Center

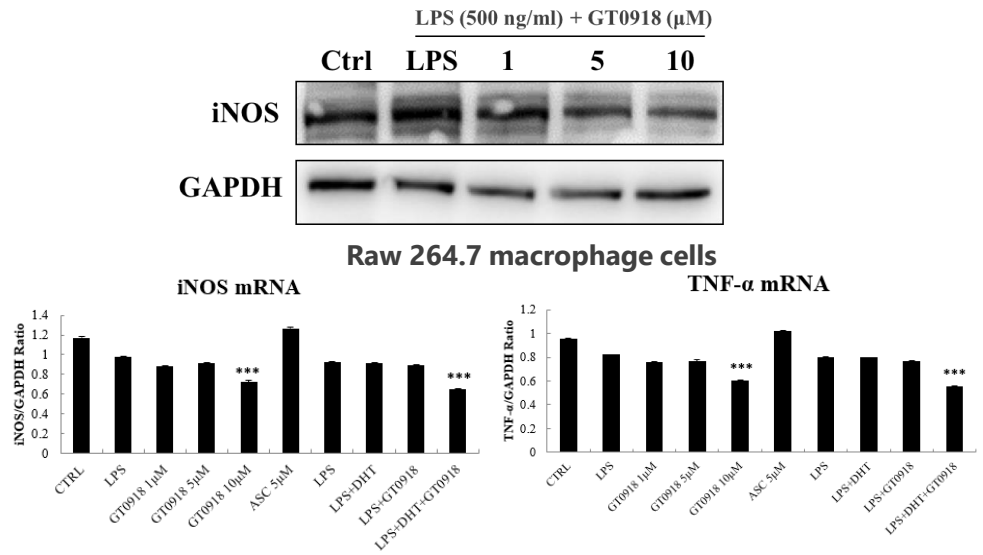
MoA of Proxalutamide (3) : Downregulates iNOS in Macrophage Cells to Inhibit Cytokine-storm

2

- *The consequent severity of COVID-19 is closely related to the iNOS-mediated cytokine-storm*



- *Proxalutamide downregulated the expression of iNOS and the mRNA of iNOS and TNF-α.*



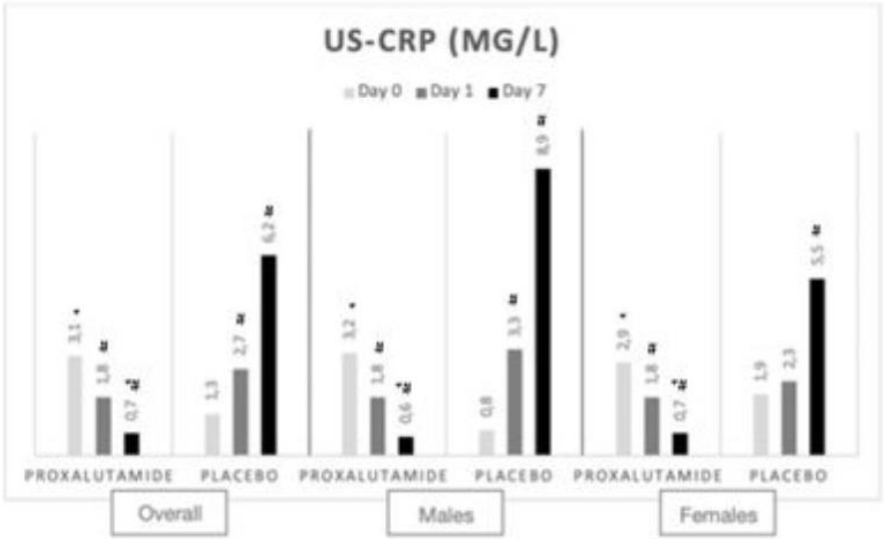
- *Proxalutamide downregulated iNOS, a marker for M1 macrophage polarization/activation, suggesting Proxalutamide can inhibit M1 macrophage mediated cytokine-storm in patients with COVID-19.*

iNOS: Inducible Nitric Oxide Synthase

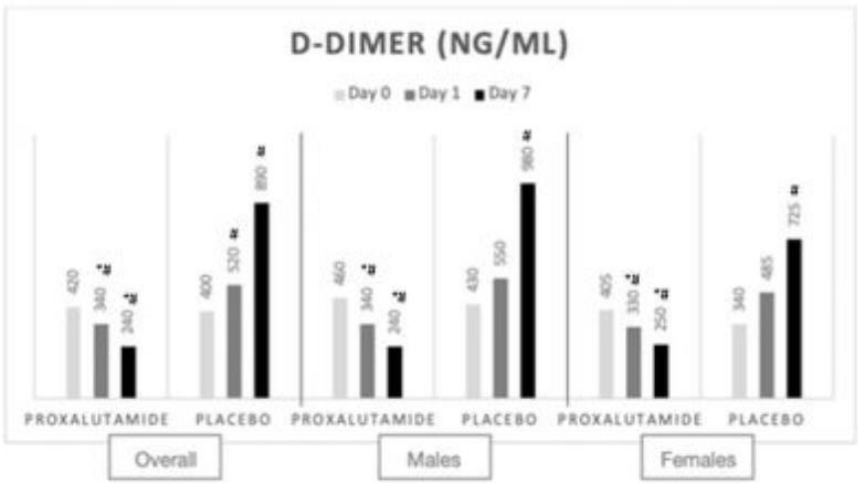
Sources: 1. Wu, Siqi et al, SSRN Electronic Journal. doi:10.2139/ssrn.3580526. ISSN 1556-5068.

MoA of Proxalutamide (3) : Significantly Reduces Inflammatory and Thrombotic Markers

2



1. Ultrasensitive C-reactive protein is a protein the liver produces in the presence of infection or inflammatory disease



2. D-dimer levels are used as a predictive biomarker for the blood disorder, disseminated intravascular coagulation and in the coagulation disorders associated with COVID-19 infection

* = p < 0.05 *versus* placebo; # = p < 0.05 *versus* day 0

Source: 1. Flavio A. Cadegiani et al, doi: https://doi.org/10.1101/2021.07.24.21261047; 2. "Assessing Cardiovascular Risk with C-Reactive Protein". *www.hopkinsmedicine.org*. 3. "D-dimer", *Wikipedia*

2 Real-World Data in Paraguay of Proxalutamide

Paraguay has granted an emergency use authorization (EUA) for proxalutamide to treat hospitalized patients with COVID-19 infections, and conducted study at Hospital Barrio Obrero, part of Paraguay's MSPBS network, for the treatment of 25 male and female hospitalized patients

Baseline

COVID-19 Ordinal Outcome Scale	***Cases（%）***
5. Hospitalized, requiring supplemental oxygen;	*18（72%）*
6. Hospitalized, on non-invasive ventilation or high flow oxygen devices;	*7（28%）*

Gender	**Cases（%）**
Male	*16（64%）*
Female	*9（36%）*

Medication

*300 mg (3 tablets*100mg/tablet) proxalutamide for continuous 14 days*

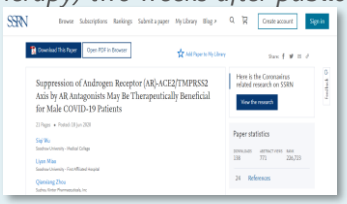
Day 14 Results

- *22 patients showed remission*
- *2 patients progressed to scale 7 with invasive mechanical ventilation*
- *1 patient died with a mortality rate of 4%, which was significantly lower than the average death rate of inpatients in Paraguay*

Conclusion:

- *The real-world data showed the promising efficacy of proxalutamide in COIVD-19 treatment*
- *We are actively exploring additional EUAs of proxalutamide in other countries and regions to benefit COVID-19 patients around the world.*

2 COVID-19 and Androgen Receptor

Journals	Articles	Contents	Notes
SSRN	*Suppression of Androgen Receptor (AR)-ACE2/TMPRSS2 Axis by AR Antagonists May Be Therapeutically Beneficial for Male COVID-19 Patients*	*Blockage of AR signaling with **AR antagonist proxalutamide (GT0918) reduced the expression of ACE2 and TMPRSS2 in normal lung cells and cancer cells derived from prostate and lung cancer**. Proxalutamide (GT0918) also inhibited the expression of inducible nitric oxide synthase (iNOS) and tumour necrosis factor-alpha (TNF α), the macrophage-activation markers, in mouse macrophage cells. These results support the role of androgen-AR signalling in the disease progression and mortality in male patients with COVID-19.*	*Published in April 2020, and ranked top ten downloads in two topics (Mechanisms of Human Disease and Anti-Infective Therapy) two weeks after publication* 
Annals of Oncology	*Androgen-deprivation therapies for prostate cancer and risk of infection by SARS-CoV-2: a population-based study (N = 4532)*	*SARS-CoV-2-infected men have a worse clinical outcome than women, and cancer patients have an increased risk of SARS-CoV-2 infection. **Prostate cancer patients receiving androgen-deprivation therapies appear to be partially protected from the infection**.*	*A retrospective study published in May 2020* 
PNAS	*Targeting transcriptional regulation of SARS-CoV-2 entry factors ACE2 and TMPRSS2*	***Androgens regulate the expression of ACE2, TMPRSS2, and androgen receptor (AR) in subsets of lung epithelial cells**. Results in this study show that targeting the transcriptional regulation of host entry factors TMPRSS2 and ACE2 is a viable treatment strategy to prevent SARS-CoV-2 infection. In particular, inhibitors of androgen receptor (AR) or bromodomain and extraterminal domain (BET) proteins are effective against SARS-CoV-2 infection.*	*Published in Nov 2020* 
Nature-communications medicine	*Characterization of SARS-CoV-2 and host entry factors distribution in a COVID-19 autopsy series*	*We detect SARS-CoV-2 virus and viral replication in pulmonary tissues by RNA-ISH and IHC and a variety of non-pulmonary tissues including kidney, heart, liver, spleen, thyroid, lymph node, prostate, uterus, and colon by qRT-PCR. We observe heterogeneity in viral load and viral cytopathic effects among various organ systems, between individuals and within the same patient. **We find ACE2, TMPRSS2 and AR expression to overlap with the infection sites.***	*Published in Aug 2021* 

Source: SSRN; Annals of Oncology; PNAS; Nature

2 The US & Intl Phase III Study for Outpatients

The Phase III Study Design (*NCT04870606*)

Sample Size: 668

Eligibility Criteria:

- *First positive SARS-CoV-2 viral infection determination ≤3 days prior to start of the first dose*
- *Not hospitalized for acute respiratory symptoms (NIAID 8-point score in 7 and 8)*
- *Age ≥18 years old*
- *Male and female[1]*

R²

1:1

Experimental:

Proxalutamide *200 mg, oral, QD, for continuous 14 days plus physician's treatment choice*

Control:

Placebo *200 mg, oral, QD, for continuous 14 days plus physician's treatment choice*

Primary Endpoints:

- *Percentage of hospitalisation events (including death) by Day 28*

Secondary Endpoints:

- *Proportion of mortality by Day 28*
- *Percentage of subjects achieving each clinical status on Days 7, 14 and 28 (NIAID 8-point scoring scale)*

**NIAID 8-point scoring scale: By National Institute of Allergy and Infectious Diseases, 1) Death; 2) Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities.*

Note: 1. FDA agreed to include female patients on May 17, 2021

2 The US, China & Intl Phase III Study for Inpatients

The Phase III Study Design (*NCT05009732*) *Sample Size: 1030*

Eligibility Criteria:

- *PCR positive in sample collected < 72 hours prior to randomization; or PCR positive in sample collected ≥ 72 hours prior to randomization, documented inability to obtain a repeat sample (due to lack of testing supplies, etc.) and progressive disease suggestive of ongoing SARS-CoV-2 infection*
- *Admitted to a hospital with symptoms suggestive of COVID-19 (NIAID 8-point score in 3 to 5)*
- *Age ≥18 years old*
- *Male and non-pregnant female*

R²
1:1

Experimental:

Proxalutamide *300 mg, oral, QD, for continuous 14 days plus physician's treatment choice*

Control:

Placebo *300 mg, oral, QD, for continuous 14 days plus physician's treatment choice*

Primary Endpoints:

- *The time to sustained recovery* is evaluated by Day 30*

Secondary Endpoints:

- *30-day mortality*

*Day of sustained recovery is defined as the first day on which the subject satisfies one of the following three categories from the NIAID ordinal scale and maintains a score of 6, 7 or 8 through Day 30.(6)Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; (7)Not hospitalized, limitation on activities and/or requiring home oxygen; (8)Not hospitalized, no limitations on activities.

2 The China, Brazil & Intl Phase III Study for Outpatients

The Phase III Study Design (*NCT04869228*)

Sample Size: 724

Eligibility Criteria:

- *Confirmed positive SARS-CoV-2 rt-PCR test ≤3 days prior to randomization*
- *Not hospitalized for acute respiratory symptoms(NIAID 8-point score in 7 and 8)*
- *Age ≥18 years old*
- *Male*

R²

1:1

Experimental:

Proxalutamide *200 mg, oral, QD, for continuous 14 days plus physician's treatment choice*

Control:

Placebo *200 mg, oral, QD, for continuous 14 days plus physician's treatment choice*

Primary Endpoints:

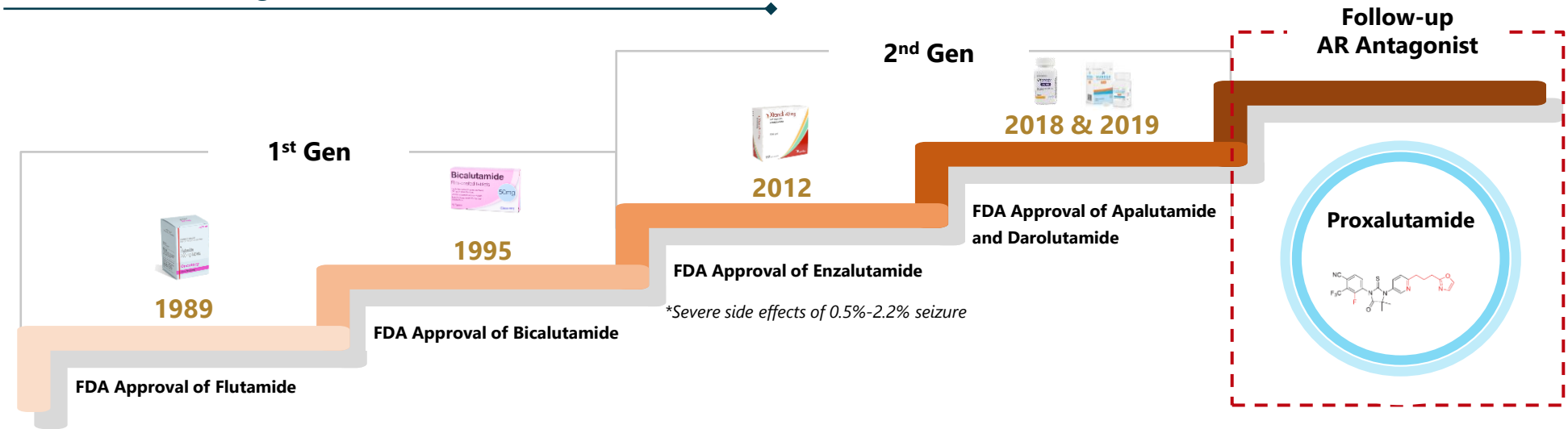
- *Percentage of subjects requiring oxygen by Day 28*

Secondary Endpoints:

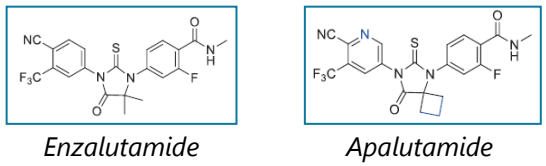
- *Percentage of subjects who experience the events(such as hospitalization, Death etc.) by Day 28 (not applicable for subjects whose countries require mild to moderate COVID-19 patients to be hospitalised, such as COVID-19 patients in mainland China)*

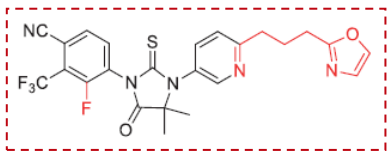
3 Proxalutamide: A Potential Best-in-Class Drug for mCRPC…

Evolution of AR antagonists



Improved molecular design





Higher in-vitro binding affinity (Ki)

- *Proxalutamide binds to the AR ligand binding domain (LBD) binding pocket with an additional hydrophobic interaction with the AR helix 12, resulting in increased binding affinity to the AR LBD*

	Proxalutamide	Enzalutamide	Bicalutamide	Apalutamide	AZD3514
Ki	14nM	48nM	160nM	N/A	2200nM

Dual-acting mechanism

- *Not only inhibits androgen from binding to AR, but also exhibits the biological effect of reducing AR expression*

Favorable safety profile

- ***Zero** incidence of triggering seizure among over **1000** users*
- *Suitable for combination therapy. Zero induction effect on CYP enzyme (CYP1A2, CYP3A4, etc,)*
- *No drug-drug interaction (DDI) with other drugs taken by mCRPC patients (chronic diseases such as diabetes, hypertension, cholesterol, etc.)*

Source: Company Prospectus, Frost & Sullivan analysis; FDA Xtandi Label

3 ...With the Potential to Become the Backbone of Future Combination Therapies for AR-related Cancers

PARP INHIBITOR

EXEMESTANE LETROZOLE FULVESTRANT

OTHER CANDIDATES

Robust and Unique Clinical Profile

- ***No induction*** *on CYP family enzymes*
- ***No reduction in drug exposure*** *in vivo*

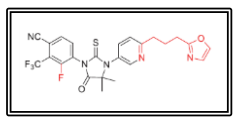
Apalutamide and its metabolite (N-desmethyl apalutamide) are moderate to strong CYP3A4 and CYP2C8 inducers

Enzalutamide is also a strong inducer of CYP3A4

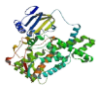
In Combination with Current Treatment

- Undergoing phase III clinical trials in China for combo therapy for mCRPC 1st line treatment with Abiraterone
- Undergoing Phase Ic clinical trials for mBC with Exemestane, Letrozole and Fulvestrant
- *Expect to commence clinical trials in combo therapy with a PARP inhibitor*

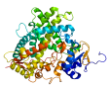
No induction



CYP3A4



CYP2B6



CYP1A2

Proxalutamide is prioritized over the other in combination therapy

Best positioned to become the preferred backbone drug candidate

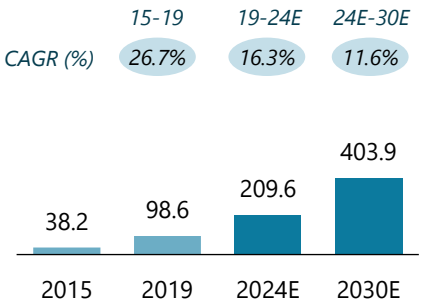
Leverage proprietary AR-related expertise to expand multiple indications in a single pipeline

Source: Company Prospectus, Frost & Sullivan analysis

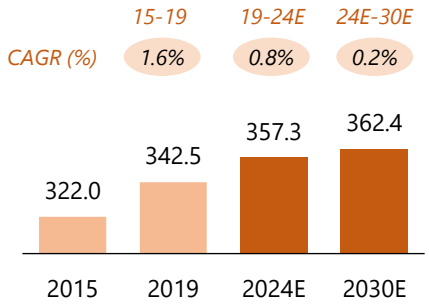
3 Proxalutamide: mCRPC

Overview of the mCRPC Market

of mCRPC Patients in China ('000)



of mCRPC Patients in the US ('000)



Key Growth Drivers

Growth in diagnosed patients *due to an ageing population and improvement of PSA screening technology*

Higher affordability of drugs *inclusion of existing drugs into the NDRL in China (i.e. Abiraterone), which is expected to boost drug sales*

Continuous launch of new drugs and Improved treatment options *(i.e. Enzalutamide and proxalutamide) into the market*

Sales of approved AR antagonists for the treatment of mCRPC

	2019 full year		2020 full year	
(in billion USD)	Global	US	Global	US
Enzalutamide	4.3	2.58	5.19	3.2
Abiraterone	2.8	0.81	2.47	0.37

Competitive Landscape

Treatment options are currently limited for mCRPC patients, with most drugs only slowing, rather than preventing the progression of the disease

AR antagonist drug candidates for mCRPC globally

Drug	Company	Status	Milestone
China			
Proxalutamide (mono and combo therapy)	Kintor	mCRPC 2nd line: Ph. III	Jul 2018 / Dec 2018
Enzalutamide	Pfizer/Astellas	mCRPC 1st line: NDA approved	Nov 2019
HC-1119	Hinova	mCRPC 2nd line: Ph. III	Mar 2019
SHR-3680(Mono/Combo[1])	Hengrui	mCRPC 2nd line: Ph. I/II	2 Feb 2016
Apalutamide	J&J	mCRPC: Ph. I	Jun 2018 Oct 2019
US			
Proxalutamide	Kintor	mCRPC 2nd line: Ph. II	Apr 2019
Enzalutamide	Pfizer/Astellas	mCRPC 1st line: NDA app.	Aug 2012
Apalutamide (combo)	Aragon/J&J	mCRPC 1st line: Phase III	Oct 2014
Darolutamide	Bayer/Orion	mCRPC 1st line: Phase I/II	Oct 2016
TRC253	Tracon/J&J	mCRPC: Phase I/IIa	Dec 2016
TAS3681	Taiho	mCRPC 2nd line: Phase I	Oct 2015
ONC1-0013B	Avionco	mCRPC: Phase I	Mar 2017

Source: Frost & Sullivan Report,financial report of Astellas/Pfizer/J&J
Note: 1. SHR-3680 combo therapy with PARP suspended

3 Proxalutamide (GT0918): Ongoing mCRPC Clinical Trials

Phase III Clinical Trials in China (Monotherapy)

CTR20180849

Design

To evaluate the impact on the rPFS and overall survival time, the safety, as well as the relationship between the discovery of biomarkers and the efficacy of proxalutamide in mCRPC ***patients who have failed Abiraterone and Docetaxel treatments***

Patient Enrolment

Multi-centre, randomised, double blind clinical trials

330 patients
from 38 sites nationwide

Experimental	**Control**
220 *patients to receive a fixed 200mg dose proxalutamide per day*	***110*** *patients to receive a placebo each day*

Each treatment cycle lasts 28 days

Co-primary endpoints

Radiographic progression-free survival (rPFS), overall survival(OS)

Phase III Clinical Trials in China (Combo-therapy with Abi)

CTR20182095

Design

To evaluate the efficacy and safety of proxalutamide's combination therapy with Abiraterone in comparison with Abiraterone in monotherapy as a ***first-line treatment for mCRPC***

Patient Enrolment

1st Phase: *Multi-centre, open, one-arm design to assess safety and tolerability*

6 patients
recruited via parallel enrolment

Test Group
Each patient was treated with 400 mg of proxalutamide in combo with 1000 mg of Abiraterone

Completed. No treatment-related DLT found.

2nd Phase: *Evaluation of rPFS, pharma-codynamic indicators, safety and others*

706 patients
recruited via parallel enrolment

353 patients	**353 patients**
Combo therapy	*Abiraterone monotherapy*

Primary endpoints

Radiographic progression-free survival (rPFS)

3 Proxalutamide (GT0918): Ongoing mCRPC Clinical Trials

Phase II Clinical Trials in US (Monotherapy)

NCT03899467

Design

*To evaluate the safety and tolerability of proxalutamide in patients with mCRPC who have **failed Abiraterone or Enzalutamide treatment***

Patient Enrolment

Multi-centre, open-label, randomised study

60 patients
In two treatment arms of 30 patients across 10 study centers

400 mg
30 patients
(including 15 of whom have failed enzalutamide and 15 of whom have failed Abiraterone)

500 mg
30 patients
(including 15 of whom have failed enzalutamide and 15 of whom have failed Abiraterone)

Endpoints

Primary endpoints: 1) recommended Phase 2 dose; 2) Number of Patients With Toxicity of proxalutamide

Secondary endpoints: 1) >50% PSA suppression; 2) percentage of radiographic disease progression; 3) radiographic and bone progression time; 4) the time to PSA progression; 5) exploratory biomarkers: cell free circulating tumor DNA (ct-DNA)/RNA (ct-RNA); 6) exploratory biomarkers: Circulating tumor cells (CTC)

3 Proxalutamide: Leveraging our AR Expertise to Expand into Treating Metastatic Breast Cancer

Overview of the Metastatic Breast Cancer Market

# of AR+ & ER+ Breast Cancer Patients ('000)

CAGR (%)	14-18	18-23E	23E-28E
	20.4%	11.0%	7.7%

# of AR+ & ER+ Breast Cancer Patients ('000)

CAGR (%)	14-18	18-23E	23E-28E
	5.9%	5.1%	4.4%

Key Growth Drivers

Increasing patient pool, *driven by deteriorating environmental conditions, unhealthy lifestyles and high levels of stress from women*

Rising demand for therapies *as patients have increased access to breast cancer screening, as detection and therapeutic technologies have improved*

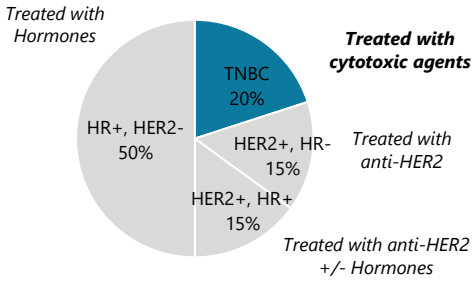
Support from insurance schemes (*i.e. the recent inclusion of new cancer drugs in the NDRL and removal of imported cancer drug tariffs in China*

AR Expression Rate From Different Breast Cancers

	AR (%)	Treatment Regimen
Luminal A	91.0%	Hormones
Luminal B	67.5%	Hormones +/- anti-HER2
HER2	58.7%	Anti-HER2
Basal-like	31.7%	Cytotoxic agents
Unclassified	46.1%	Cytotoxic agents

Competitive Landscape

Breast cancer is a disease that can take on many different forms. There are currently 5 major types of breast cancer and 4 main treatment types



TNBC

- TNBC generally grows faster than other breast cancers
- As TNBC lacks a clear drug target, some patients experience poor efficacy from chemotherapy and relapses are more likely to occur
- TNBC represents a major potential market for AR antagonists

AR Antagonists Currently Undergoing Clinical Trials for Metastatic Breast Cancer

Drug	Indication	Company	Status
China			
Proxalutamide	AR+ breast cancer	Kintor	Phase I
US			
Enzalutamide	Advanced, AR+ TNBC	Pfizer/Astellas	Phase II
Enzalutamide/Trastuzumab	HER2+, AR+ metastatic/ advanced breast cancer	Astellas	Phase II
Enzalutamide/Taxol	Stage I-III AR+ TNBC	Astellas	Phase II
Enzalutamide	Early Stage AR+ TNBC	Astellas	Phase II
Bicalutamide	AR+,ER-, PR- metastatic breast cancer	AstraZeneca	Phase II
Palbociclib/ Bicalutamide	AR+ metastatic breast cancer	Pfizer	Phase I/II
Taselisib/Enzalutamide	AR+ metastatic TNBC	Genentech	Phase I/II
Alpelisib/Enzalutamide	AR+ and PTEN+ metastatic breast cancer	Novartis/ Astellas	Phase I

Source: Frost & Sullivan Report

3 Proxalutamide: Metastatic Breast Cancer

Phase Ic Clinical Trials in China (CTR20191063)

To evaluate the safety, pharmacokinetic characteristics and initial efficacy of Proxalutamide in combination with Exemestane, Letrozole and Fulvestrant in patients with HR+ and AR+ metastatic breast cancer

Stage 1: Introduction Period *to collect pharmacokinetics data of individual drugs*

Letrozole	Exemestane	Fulvestrant
14 days (6 patients)	*14 days (6 patients)*	*28 days (6 patients)*

Stage 2: Combination Therapy Period *wherein Proxalutamide and the combo therapy drug will be administered with two 4 week (28 days) treatment cycles*

1st Cycle
Subjects will receive a DLT assessment during the 1st cycle of combination therapy

→

2nd Cycle
Subjects will undergo a tumour imaging evaluation at the end of the 2nd cycle of treatment

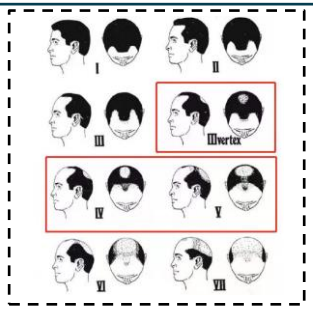
Stage 3: Extended Treatment Period *after the completion of 2 treatment cycles*

Extended Treatment
If a subject's disease is clinically relieved or stable and well tolerated and if the subject is willing to continue taking the test drug, the investigator may continue to give the patient extended treatment until there is disease progression

Source: Prospectus

4 Pyrilutamide: Utilizing our Proprietary AR Capabilities to Address Androgenic Alopecia

Androgenic alopecia – A growing concern globally



- *Common form of scalp hair loss affecting **both men and women***
- ***Rapidly growing** concerns among all age group due to lifestyles and stress*

Stage IIIvertex-V in Norwood–Hamilton scale

	Prevalence[1]	Market potential[2]
China	134 million	*Market Size of Drugs Approved for Androgenetic Alopecia* ***CNY5.04bn** in 2028*
US	83 million	*Market Size of Drugs Approved for Androgenetic Alopecia* ***US$1.4bn** in 2028*

Underpenetrated market lack of novel treatment

Androgenetic alopecia is a common form of scalp hair loss that affects both men and women

Finasteride
Approved for androgenetic alopecia by the US FDA in 1997

Minoxidil
Approved for androgenetic alopecia in 1988 and as an OTC drug in 1996 by the US FDA

Only two products* *available in the market for androgenic alopecia, and no novel treatment approved in the last **22 years***

* *Dutasteride was approved for the treatment of AGA by South Korea and Japan in 2009 and 2015 separately, but was approved by FDA only for the treatment of benign prostatic hyperplasia (BPH) in 2001*

Significant limitations and side effects in current treatments

Finasteride	Minoxidil
• Severe **sexual adverse effects**	• Fragmented market after patent expiry in 1998
• **Orally** taken drug	• **No clear MoA**
• Only approved and found effective for use in men	

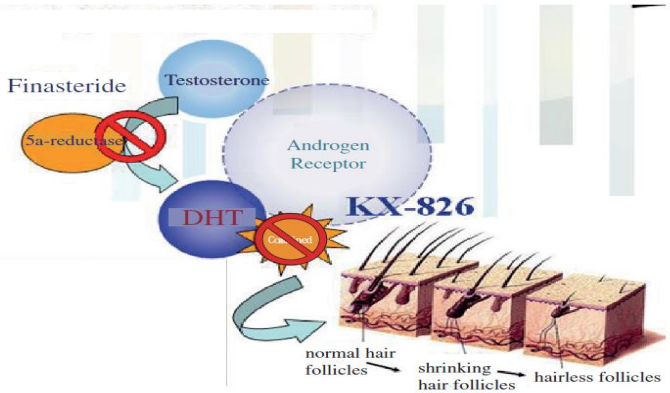
- ***Strong demand** by people with AGA for the medical treatment with **proven efficacy** and **safety***
- ***Treatment rate** for hair loss remains **high** and is expected to **improve** consistently each year*
- *OTC options and hair transplant are **rapidly growing** due to the **lack of effective** and **safe** medical options*

Source: Company Prospectus, Frost & Sullivan analysis,
Note: 1. Data in 2019 2. Refer to drugs (excluding consumer goods) 3. USD/CNY = 6.67

4 Pyrilutamide: Androgenetic Alopecia

Mechanism of Action

*The combination process of **DHT and receptors affects the hair follicle cells**, which leads to obstruction of hair follicles and results in the shrinkage of hair follicles due to their ability absorb nutrients. It leads to excessive hair loss, and eventually to baldness without immediate therapy.*



*KX-826 is being developed for topical application to locally block the androgen mediated signalling **by competing androgen to bind to AR** in the targeted tissues instead of reducing androgen levels systemically*

Results from Previous Clinical Trials

Phase I/Ib clinical trials in China and US

- ✓ ***Safety:** There were **no ≥ grade 3 SAE**. All AEs related to the drug were "contact dermatitis" **and all were mild**, which recover/heal in a short time. The contact dermatitis may be caused by excipients.*
- ✓ ***PK:** The **blood concentration is extremely low**.*

Clinical Trials in Plan

- *Expected to release detailed data of phase II clinical trials for AGA male adults in China (CTR20201655)*
- *Expect to conduct phase III clinical trial for male AGA adults and phase II clinical trial for female AGA adults in Q4 2021 in China*

Phase II Clinical Trials For AGA Male Adults In China

Design

Assess the safety and efficacy of pyrilutamide for treatment of Chinese adult male androgenetic alopecia subjects.

Subjects Enrolment

Multicentre, randomised, double-blind, placebo control clinical study

120 subjects

30 subjects	30 subjects	30 subjects	30 subjects
(2.5mg) 0.25% Pyrilutamide BID	*(5mg) 0.5% Pyrilutamide QD*	*(5mg) 0.5% Pyrilutamide BID*	*Placebo*

Evaluation Frequency

*Evaluate **every six weeks** from the commencement of the administrating the drug until the end of the 24th week.*

Source: Company Prospectus, CDE

Pyrilutamide: Utilizing our Proprietary AR Capabilities to Address Acne Vulgaris

4

Robust Clinical Profile Target to Redefine the Market

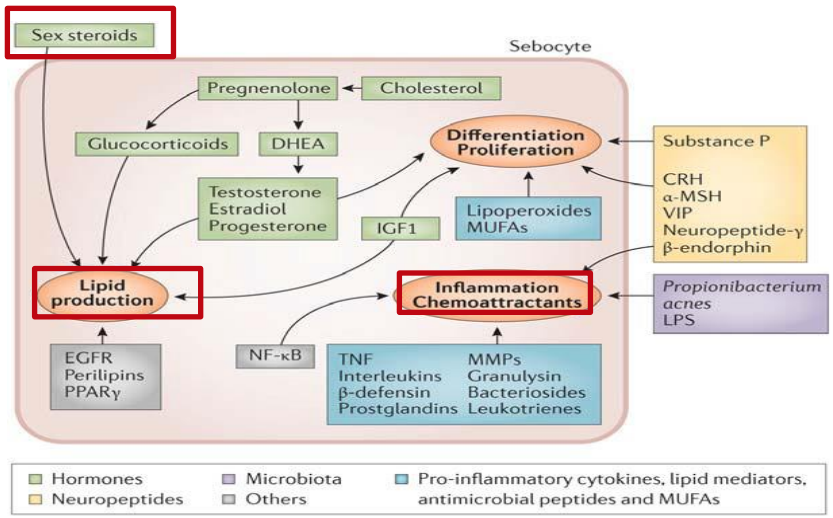
Acne vulgaris is a chronic inflammatory dermatosis notable for open or closed comedones and inflammatory lesions

Hormonal agents, topical therapies, systemic antibiotics and isotretinoin are the prescribed treatment options

150+ million

Prevalence of acne globally aging 10 to 25 in 2018

Pathophysiological Processes



- *The pathogenesis of acne involves several processes, including sebum production and sebocyte differentiation, proliferation, and inflammation.*
- *These processes are regulated by circulating sex hormone levels as well as locally synthesized hormones, neuropeptides, the microbiota, and pro-inflammatory cytokines, lipid mediators, antimicrobial peptides, and monounsaturated fatty acids (MUFAs).*

Ongoing Clinical trials

- *Received IND approval for acne vulgaris in China, and completed first subject enrolment of phase I/II trial in Apr 2021*
- *Expect to complete phase I/II trial and commence phase III trial in 2022*

Phase I/II clinical trials in China CTR20210427

Design

Evaluate the safety, tolerability, pharmacokinetics, and efficacy of pyrilutamide in subjects with mild to moderate acne vulgaris

Subjects Enrolment

Randomized, double-blind, placebo-controlled clinical study

216 subjects

0.25% Pyrilutamide gel QD	*0.25% Pyrilutamide gel BID*	*0.5% Pyrilutamide gel QD*	*0.5% Pyrilutamide gel BID*
1% Pyrilutamide gel QD	*1% Pyrilutamide gel BID*	*Placebo QD*	*Placebo BID*

Primary endpoints

Phase I: Tolerability and safety (contact dermatitis, AEs, etc.)

Phase II: Efficacy and safety (IGA Scale, facial sebum level, AEs, etc.)

*IGA: Investigator Global Assessment

Source: Company Prospectus, Frost & Sullivan analysis, CDE

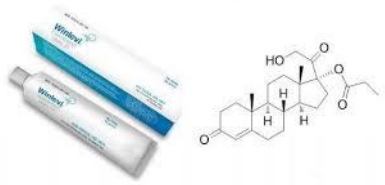
Mechanism of AR Inhibitors for AGA and Acne Treatment Proven

4

Case Study - Cassiopea

*27 Aug 2020, Cassiopea announced that the US FDA has approved a new drug application for its Clascoterone (1% concentration) cream for the treatment of **acne**. Will be available in Q4 2021.*

This is the first new mechanism drug for acne treatment approved by FDA in the past 40 years. Patent will expire in 2028.

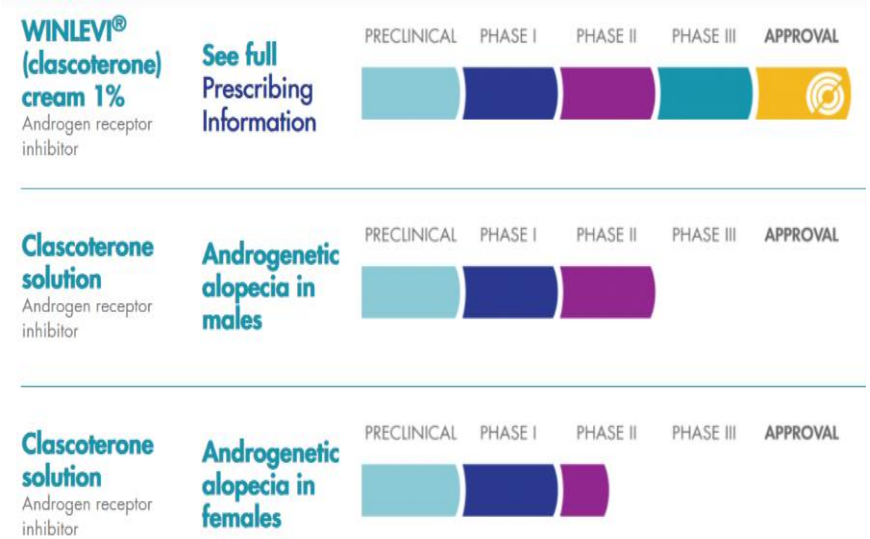


MoA

*Clascoterone is a "first-in-class" androgen receptor (AR) inhibitor for external use. The chemical **competes with androgens**, particularly DHT, and with the sebaceous glands and androgen receptors within the hair follicles. Clascoterone **inhibits lipid production** in cultured sebocytes and **reduces pro-inflammatory cytokines** affected by androgens.*

Indication of AGA

*Cassiopea is conducting clinical trials for treatment of **AGA** with Clascoterone. The phase II clinical trial **for male** had completed and submitting phase III protocol to FDA. The phase II clinical trial **for female** completed and will obtain data in Q3 2021.*



Source: Cassiopea official web, Press Release, Yahoo Finance

5 ALK-1: Potential First-in-class Fully Human Mab

Addressing Limitations in Existing VEGF Inhibitors with the Potential to Become a Complementary Combo Drug for Solid Tumours

ALK-1 is a fully humanised IgG2 neutralising monoclonal antibody for vascular endothelial cells ALK-1 and can both inhibit the growth of tumour vessels / reduce their blood flow and vascularisation by blocking its receptors and alter the tumour microenvironment

Anti-angiogenic Drugs and Limitations of VEGF Inhibitors

Due to its efficacy & milder side effects, anti-angiogenic drugs (i.e. VEGF inhibitors) have become a key treatment for liver cancer

The most common VEGF inhibitors are

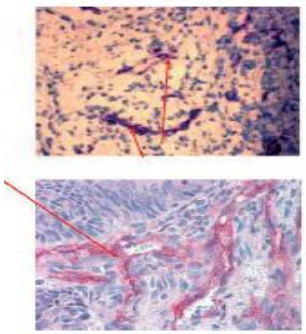
- *Bevacizumab*
- *Sorafenib*
- *Axitinib*

However, certain patients develop VEGF resistance, rendering VEGF inhibitors ineffective in treating the cancer

ALK-1 Pathway as a Potential Escape Path

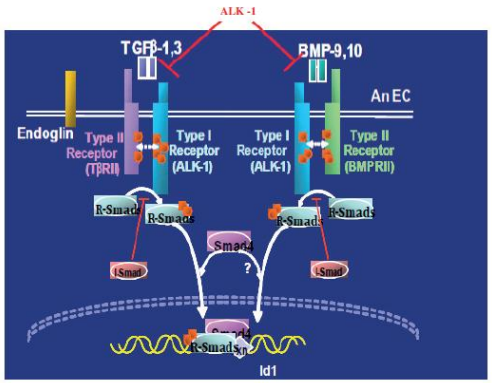
Research has hypothesized that the ALK-1 pathway may allow tumours to escape from the effects of VEGF inhibitors

ALK-1 overexpression in human breast and colon tumours



Potential Opportunity to Solve an Unmet Medical Need

As such, ALK-1 signalling may also be a complementary angiogenesis pathway to be activated upon VEGF resistance



ALK-1 antibody received the exclusive global license from Pfizer in 2018 for development, production and commercialization, which also covered all types of cancers. It received grants from the National Science and Technology Major Project of the Thirteenth Five-Year plan.

Latest Clinical Progress of GT90001:

Combination therapy with a PD-1 for metastatic HCC commenced in May 2019 in Taiwan

Clinical Trial Design of Phase II

- *Stage 1: GT90001 (7、4.5、 3 mg/kg) +Nivolumab (3 mg/kg), 6 patients/group, if no DLT was observed, move on to stage 2*
- *no DLT was observed, move on to stage 2*
- *Stage 2 (Expansion Cohort): 14 patients*
  Primary Endpoints: Safety, Tolerability
  Secondary Endpoints: ORR, DOR, DCR, TTR

Preliminary result:

The results showed that among the 20 evaluable patients, eight patients (40.0%) were observed partial remission (PR). The side effects were well tolerated and manageable. The pharmacokinetic parameters of GT90001 and Nivolumab are similar to those of monotherapy.

Source: Company Prospectus

5 ALK-1 (GT90001): Metastatic HCC

Study Design: *a phase I/II, open-label, single arm,dose de-escalation and expansion trial of GT90001 in combination with Nivolumab (NCT03893695)*

Study Population:

- *HCC with at least one measurable lesion.*
- *BCLC C or B (refractory or not amenable to locoregional therapy).*
- *Have documented disease progression or intolerance after first-line systemic treatment with Sorafenib or Lenvatinib*
- *Child-Pugh score ≤ 6.*
- *ECOG performance status: 0-1.*

Primary Endpoints

- *Safety and tolerability*

Secondary Endpoints

- *ORR (investigator)*
- *DOR, DCR, TTR, PFS (investigator)*
- *PK profile*

Stage One: Safety evaluation

GT90001

- *7.0 mg/kg, iv, Q2W*

Nivolumab

- *3.0 mg/kg, iv, Q2W*

Cohort A, N = 6, no DLT

SMC

GT90001

- *4.5 mg/kg, iv, Q2W*

Nivolumab

- *3.0 mg/kg, iv, Q2W*

SMC

GT90001

- *3.0 mg/kg, iv, Q2W*

Nivolumab

- *3.0 mg/kg, iv, Q2W*

Stage Two: Dose Expansion

- ***Subject Population:*** *same as stage one* ***N = 14*** *(enrollment completed in June 2020)*
- ***Treatment:***
  GT90001 *7.0 mg/kg, iv, Q2W*
  Nivolumab *3.0 mg/kg, iv, Q2W*

5 ALK-1 (GT90001): Metastatic HCC (cont'd)

Safety Results

Table 2. AEs occurring in ≥10% of patients (N = 20)

update date: 30-Sep-2020

	All AEs(N=20) N（%）		***Treatment-related AEs(N = 20) N（%）***	
	All Grades	***≥ Grade 3***	***All Grades***	***≥ Grade 3***
Platelet count decreased	*11(55)*	*3(15)*	*11(55)*	*3(15)*
Pruritus	*9(45)*	*-*	*8(40)*	*-*
Rash	*7(35)*	*2(10)*	*7(35)*	*2(10)*
Aspartate aminotransferase increased	*3(15)*	*1(5)*	*3(15)*	*1(5)*
Epistaxis	*3(15)*	*-*	*3(15)*	*-*
Fatigue	*5(25)*	*-*	*2(10)*	*-*
Blood bilirubin increased	*3(15)*	*-*	*2(10)*	*-*
Hot flush	*3(15)*	*-*	*2(10)*	*-*
Headache	*2(10)*	*-*	*2(10)*	*-*
Alanine aminotransferase increased	*2(10)*	*-*	*2(10)*	*-*
Blood thyroid stimulating hormone increased	*2(10)*	*-*	*2(10)*	*-*
Eosinophilia	*2(10)*	*-*	*2(10)*	*-*
Hyperthyroidism	*2(10)*	*-*	*2(10)*	*-*

- *No DLTs were observed in the cohort A in dose de-escalation phase.*
- *In total, 20/20 (100%) patients ≥1 treatment-related AE, mainly mild to moderate and easily manageable.*
- *Treatment related grade 3-4 AEs were reported in 6 patients (30%), including platelet count decreased (n=3, 15.0%), skin rash (n=2, 10%), Aspartate aminotransferase increased(n=1,5%). No grade 5 AEs reported.*
- *3 patients (15%) experienced treatment-related SAEs (renal dysfunction G2, hepatitis G2, hyperamylasemia G2).*

5 ALK-1 (GT90001): Metastatic HCC (cont'd)

Efficacy Results

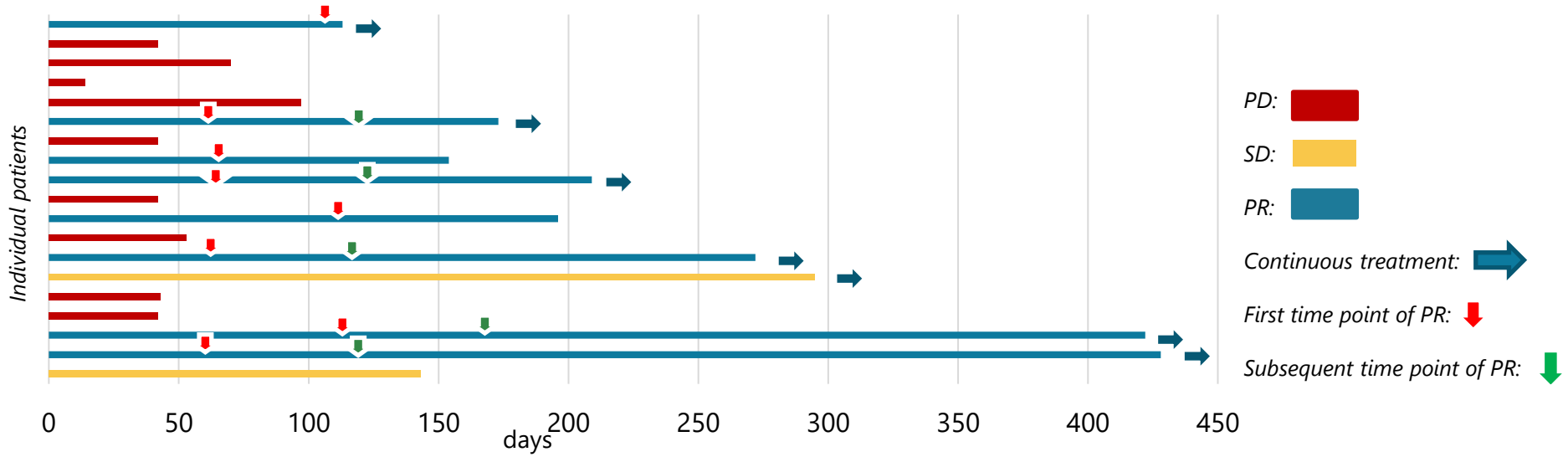
Table 3. Preliminary efficacy results

update date: 30-Sep-2020

GT90001 (7 mg/kg) + Nivolumab (3 mg/kg)	PR (N = 20)	ORR (N = 20)	ORR (confirmed) (N = 20)	SD≥16weeks (N = 20)	DCR (N = 20)	DOR（N=8）	
						> 12months	>6months
Number (%) of Patients	40% (8/20)	**40%** (8/20)	25% (5/20)	10%(2/20)	50% (10/20)	12.5%（1/8）	37.5（3/8）

- As of 30th Sep. 2020, all 20 patients had received at least one non-baseline tumor evaluation.
- Eight (8) patients achieved PR while five (5) pts achieved confirmed PR. One patient has not yet reached confirmed PR.
- Six(6)patients remain on responding status.

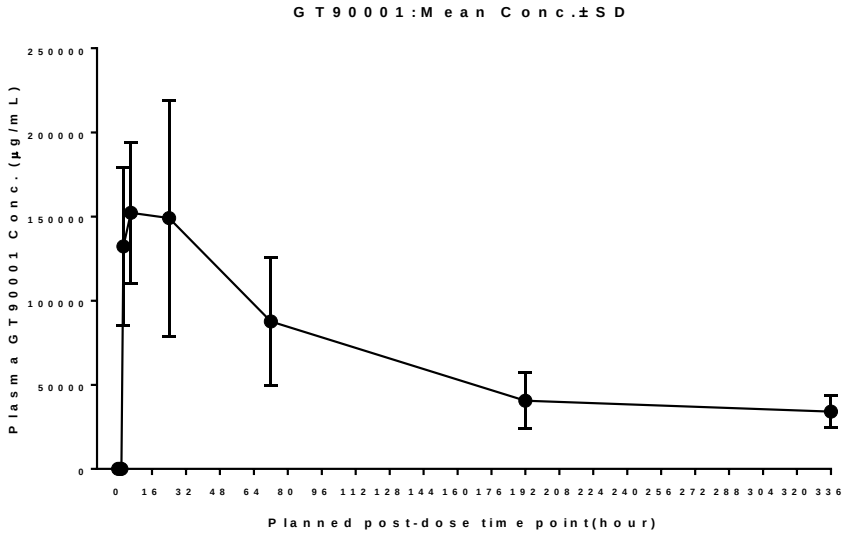
Treatment Duration in Individual Patient

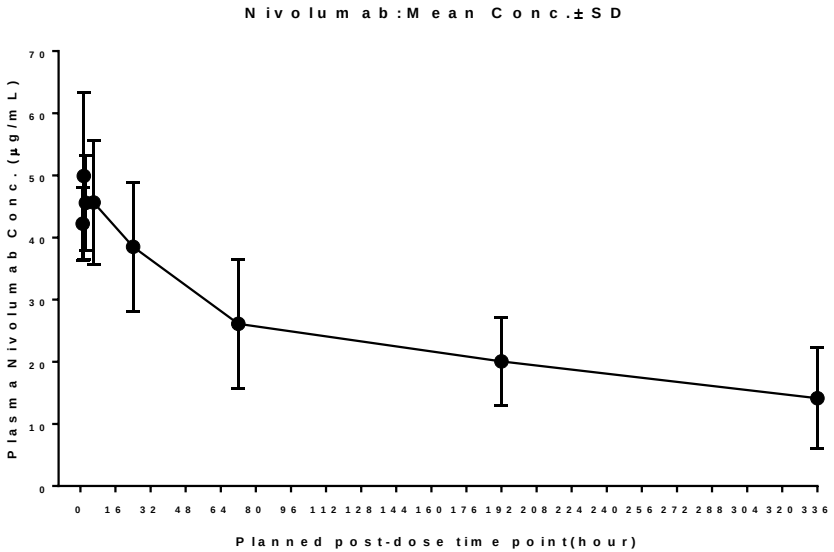


- One (1) patient with 1-time study drug administration is excluded from the figure with best response of progression disease.
- All patients who ended treatment were due to disease progression.

5 ALK-1 (GT90001): Metastatic HCC (cont'd)

PK Analysis





- *In the combination, the pharmacokinetics of GT90001 and nivolumab were similar to those observed in monotherapy.*
- *Serum concentrations declined in a bi-exponential manner over the course of the treatment interval.*
- *GT90001 was slowly eliminated from the circulation.*

Table 4. PK pharmacokinetic parameters*

**Geometric Mean, Geometric Coefficient of Variation(%)*

Tested Drug	*AUC_{0-t} (hr*μg/mL) N=6*	*CL (mL/hr/kg) N=6*	*$T_{1/2}$ (day) N=6*	*C_{max} (μg/mL) N=6*
GT90001	*20160.9 ± 37.8*	*0.23 ± 0.08*	*10.1 ± 5.1*	*159.3 ± 42.3*
Nivolumab	*7043.7 ± 46.1*	*0.179 ± 0.054*	*16.3 ± 4.3*	*50.3 ± 23.6*

6 Detorsertib: mTORC1 and mTORC2 Dual Inhibitor

Highlights

- *Detorsertib is a second-generation mTOR inhibitor that **inhibits both mTORC1 and mTORC2***
- *Has **shown greater therapeutic advantages** as compared with first-generation mTOR inhibitors that only inhibit mTORC1.*
- *There was **no mTORC1/mTORC2 dual inhibitor** that had been approved for marketing globally.*

Global ongoing clinical studies on mTORC1/2 dual inhibitor

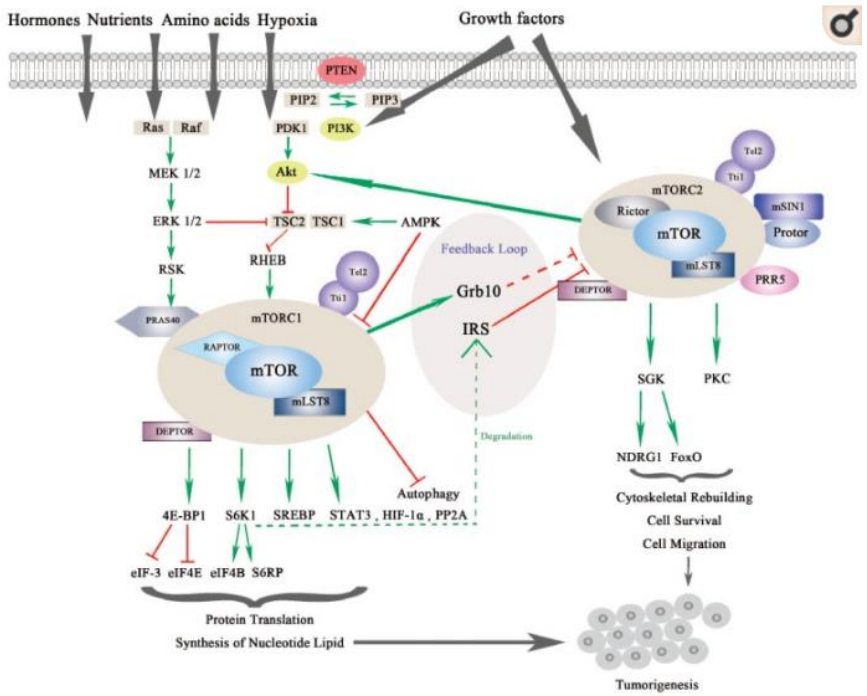
Drugs	Company	Stage/Indications/Locations
Onatasertib (CC-223)	*Antengene & Celgene*	• *Phase 2: NSCLC[a], US* • *Phase 2: HCC[b], China/US/S Korea* • *Phase 2: MM, US* • *Phase 2: Non-Hodgkin lymphoma, US* • *Phase 1: Diffuse large B-cell lymphoma, EU/US*
Detorsertib	***Kintor***	• ***Phase 1:* Leukaemia and BCC, *China/US***
DFN-529	*Diffusion Pharma*	• *Phase 1: Age related macular degeneration, US*
XP-105	*Xynomic*	• *Phase 1: Solid tumor, Germany/Belgium/Italy*
SCC-31	*Shandong Luoxin*	• *Phase 1: Metastatic breast cancer*

a. CC-223 combo with Erlotinib or Azacitidine; b. CC-223 mono.

Other drug candidates are in pre-clinical stage

- *CMG-101(developed by CHA University, S. Korea, treatment for RCC)*
- *mTOR inhibitor (developed by Nankai University)*

MoA



*The **PI3K/AKT/mTOR signalling pathway** helps regulate various cellular functions, including cell proliferation, differentiation, apoptosis and nutrition.*

First generation mTOR inhibitor only inhibits mTORC1 and has no efficacy on mTORC2, which can cause the activation of oncogene AKT and AMPK and drug resistance through mTORC2.

*Detorsertib can **compete with the catalytic site of mTOR for ATP**, reducing the toxicity of dual inhibition of PI3K/mTOR without affecting the feedback pathway such as AKT.*

Source: Zhang et al, Int J Mol Sci, 2019, prospectus

6 GT1708F: Hedgehog Signaling Pathway SMO Inhibitor

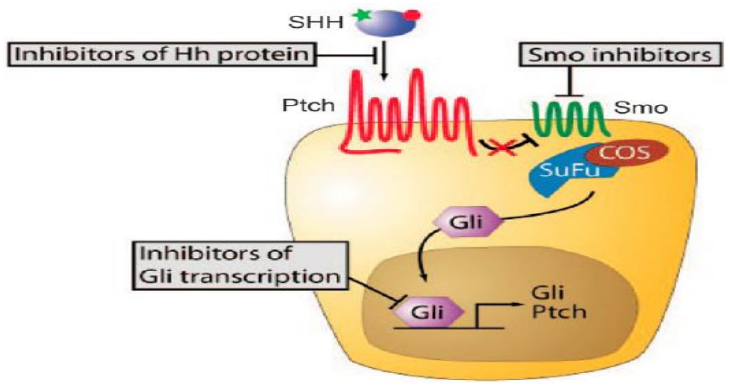
MoA

Tumour cells have abnormal activation of Hedgehog signalling pathway (PTCH, the patched, deletion or SMO overexpression) and overexpression of the target gene.

The occurrence of medulloblastoma and basal-cell carcinoma are associated with abnormal activation of the Hedgehog signalling pathway.

The Hedgehog signalling pathway is activated by up-regulating SMO in acute myeloid leukaemia cells and chronic myeloid leukaemia stem cells

The occurrence of chronic myeloid leukaemia in a mouse model can be reduced through the inhibition of SMO.



Competitions

*Three approved SMO inhibitors in US/EU: **Glasdegib for AML** (Pfizer), **Sonidegib for BCC** (Novartis/Sun), **Vismodegib for BCC** (Genentech/Roche).*

Drugs in clinical stage globally

Drug	Active Company	Global Dev.
Glasdegib	Pfizer	• Phase III, China
Sonidegib	Novartis AG; Sun Pharmaceutical Industries Ltd	• Phase 2: Basal cell nevus syndrome, US; Myelofibrosis: Switzerland • Phase 1: Myelodysplastic syndrome: France
Vismodegib	Genentech Inc; Roche Holding AG	• Phase 2: Meningioma / Head and neck tumor, US • Phase 1: Odontogenic tumor, US
patidegib (topical gel)	PellePharm Inc	• Phase 3: Basal cell nevus syndrome, US • Phase 2: BCC, US/UK
NLM-001	Nelum Corp	• Phase 2: Pancreas tumor, US

Kintor ranks the second among clinical trials in China

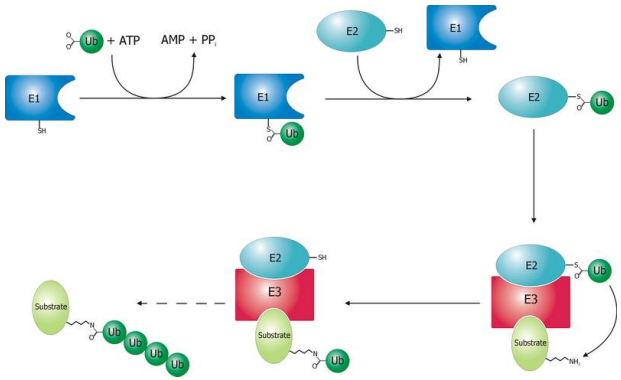
NO.	Drug Name	Active Company	Dev. in China
1	Glasdegib	Pfizer Inc	AML: Phase III
2	**GT-1708F**	**Kintor Pharmaceutical Ltd**	**Leukaemia and BCC: Phase I**
3	deuterated vismodegib analogs	Hinova Pharmaceuticals Inc	Preclinical
4	hedgehog signaling pathway inhibitors	Simcere Pharmaceutical Group	Preclinical
5	IMP-5471	IMPACT Therapeutics Inc	Preclinical
6	hedgehog pathway inhibitors	Zhejiang Academy of Medical Sciences	Preclinical
7	hedgehog signaling pathway inhibitors	Fudan University	Preclinical

Source: Prospectus

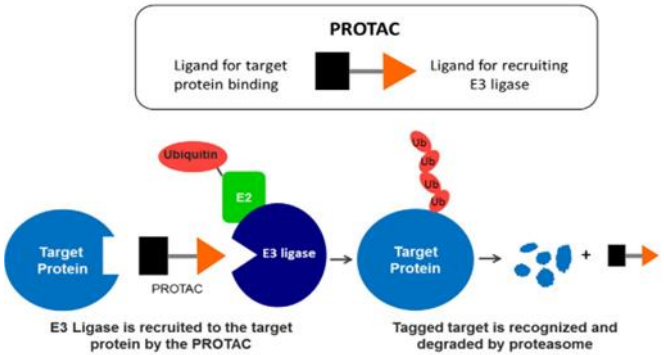
6 PROTAC: Emerging Technology in Drug Discovery

PROTAC: PROteolysis TArgeting Chimera

Ubiquitinproteasome system(UPS) is a natural protein degradation process



PROTAC hijacks UPS in the cell to degrade target protein



- *Much of the turnover of protein in cells is mediated by the UPS.*
- *Using the UPS to induce degradation of specific target proteins has been studied for decades.*
- *PROTACs are heterobifunctional compounds comprising a recruiting element for a protein of interest (POI) and an E3 ligase recruiting element bound together via a linker. By bridging the gap between a POI and an E3 ligase and inducing their proximity, PROTACs can induce the ubiquitination of the POI and then degrading POI.*

6 GT20029: Androgenetic Alopecia and Acne Vulgaris

MOA of GT20029

GT20029 is a AR-PROTAC compound developed by using our in-house Protac platform. It can selectively degrade Androgen Receptor in cell based assays. It will be applied locally to affected areas for treatment.

Advantage of GT20029

GT20029 has the totally different MOA for treating androgenetic alopecia and acne vulgaris. It has the potential to redefine the market given its treatment avoids notable side effects that have deterred users from accepting the treatment

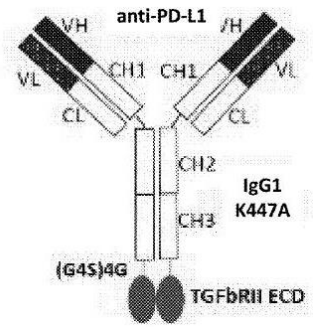
It has all the advantages that pyrilutamide has over other treatments currently on the market.

Additionally:

- *GT20029 could not permeate through skin owing to its physical properties and its blood level is undetectable while applied on the skin of the animals. Thus devoid of any mechanism based side effect.*
- *GT20029 shows potential in degrading mutant AR protein which will benefit the post AR antagonist treated patient.*
- *Since the protein will take time to regenerated once it is depleted, the treatment could last longer than antagonist.*
- *By circumventing the oral bioavailability problem of Protac molecule and pinpoint the effect protein degradation, this molecule has the potential to prove, for the first time, the effectiveness of Protac technology in drug discovery.*

6 PD-L1 / TGF-β Dual Targeting Antibody

Advantage in Composition



*With a high activity in **inhibiting both PD-L1 and TGF-β**.*

*Genetic engineering modification could reduce its degradation or fragmentation in CHO cell expression proteins, which makes it easier to be commercially produced and becomes a **potential "best-in-class"** drug*

Potential Indications and Market Opportunities

Could be treatment for a variety of solid tumours, including:

Non-small cell lung cancer (NSCLC) 1L/2L
Lung cancer is one of the malignant tumors with the highest incidence and number of deaths. Among them, NSCLC accounts for more than 85%

Biliary tract cancer (BTC) 1L/2L
From 2019 to 2023, the CAGR of the global BTC treatment market will be close to 6%

Cervical cancer (CC) 2L
CC ranks the second in mortality rate of cancers among women. About 500,000 women are newly diagnosed with cervical cancer every year globally.

Nasopharyngeal carcinoma (NPC)
NPC is one of the high incidence of malignant tumors in China, and the incidence rate ranks the first among tumors of otolaryngology

Competitive Landscape

No new drugs have been approved. The fastest clinical trials in progress around the world are by Merck KGaA

- Merck KGaA - Bintrafusp alfa

Indications	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA
NSCLC[1]						
BTC[2]						
Cervical cancer						
Multiple types of solid tumours						

Note: 1. Merch announced discontinuation of phase III trial on Jan 20, 2021 for failure to meet the co-primary endpoint
2. Announced on Mar 16, 2021 that failed to meet the ORR threshold for regulatory filing in 2L treatment, and announced on Aug 23, 2021 that failed to meet the primary endpoints in 1L treatment

Drug candidates	Company	Stage
China		
GT90008	*Kintor Pharma*	*I*
SHR-1701	*Hengrui Medicine*	*II*
PM8001	*Pumis Biotechnology*	*I/II*
TQB2858	*Chia Tal-tianqing*	*I*
QLS3901	*Qilu Pharmaceutical*	*I*
Y101D	*YZY Biopharma*	*I*
TST005	*Transcenta*	*I*
BR102	*Brightgene Bio-medical*	*I*
BJ-005	*BJ Bioscience*	*I*

Source: Merck KGaA Official Web, CDE, Technavo market research reports, Press Release

7 Integrated R&D Platform Spearheaded By Top Scientists

Dr. Youzhi Tong
Chairman, CEO & Founder

- 25+ years of experience in biopharm R&D and management
- Former VP of Angion Biomedica in the U.S.
- Former Assistant professor of Albert Einstein College of Medicine
- Ph.D. in pharmacology from Cornell; MA and BA in Chemistry from PKU

Angion Biomedica corp | EINSTEIN Albert Einstein College of Medicine

Dr. Xunwei Dong (M.D.)
Chief Medical Officer

- 18+ years medical related experience in Novartis, Pfizer and GSK
- Previous Clinical Development Medical director of Novartis
- 10 years experience as an attending surgeon
- M.D. from Peking Union Medical College

NOVARTIS | Pfizer | gsk

Dr. Qun Lu
Chief Technology Officer

- 20+ years of experience in CMC development in Pfizer, Merck and Celgene Corp./BMS
- Member of the board of directors of International Consortium for Innovation and Quality in Pharmaceutical Development
- Ph.D. in Physical Chemistry at Arizona State University; BA in Chemistry from PKU

Bristol Myers Squibb | Celgene | Pfizer | MERCK

Lucy Lu
Chief Financial Officer

- 13+ years of experience in investment banking
- Former head of investment banking and managing director at GF Capital
- Executive director in the Asian healthcare group at UBS
- MA in Finance from Peking University; BA in Finance from Renmin University of China

廣發融資(香港)有限公司 GF CAPITAL (HONG KONG) LIMITED | UBS | CREDIT SUISSE

7 Integrated R&D Platform Spearheaded By Top Scientists

Liandong Ma
Vice President,
Head of Institute of R&D

- Former senior scientist of Eli Lilly and Company
- 20+ years of experience in the development of new oncology drugs, leading and participating in more than 10 oncology drug R&D projects, and bringing 4 drugs to the clinical stage
- MA and BA in medicine from Harbin Medical University

Dr. Ruo Xu
Vice President
R&D (Chemistry)

- 20+ years of experience in the pharmaceutical industry
- Former Chief Scientist of Schering-Plough, and worked in Merck for more than 15 years
- Responsible for the design and synthesis of more than 7 small molecule inhibitors
- Ph.D. in chemistry from Columbia University; BA in chemistry from Peking University

Dr. Jianfei Yang
Vice President
R&D (Biologics)

- 17+ years of experience in Boehringer-Ingelheim and GSK in immune-related drug R&D
- Published 12 papers as corresponding authors and holds 4 patents
- Ph.D. in pathology from Niigata University School of Medicine

Dr. Jiawen Han (M.D.)
Vice President
Business Development

- 25+ years of experience in drug development and business operations
- Former VP of Qilu Boston and Wuxi AppTec Pharmaceutical Inc
- M.D. from Peking University, Ph.D. from University of Rochester School of Medicine

Juping Shen
Deputy General Manager

- 30+ years of experience in the pharmaceutical industry
- Worked in Otsuka, Eisai, Chiatai Tianqing, Sanhome, Fresenius Kabi
- MA from East-South University; BA from Chinese Pharmaceutical University

Dr. Jie Chen
Deputy General Manager,
Joint Company Secretary

- 10+years of experience in drug R&D
- Published nearly 20 papers and holds 4 patents
- Working as guest researcher at Suzhou Research Institute of LICP
- Ph.D. in organic chemistry from Chinese Academy of Sciences

7 Integrated R&D Platform Spearheaded By Top Scientists

Dr. Jianhua Shen
Analytical Development
Senior Director

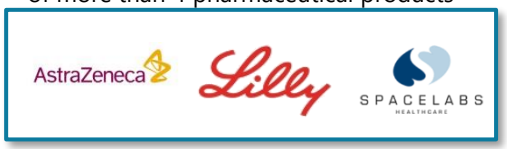
- 20+ years of experience in analytical R&D management in pharmaceutical industry
- Worked for Synta and Inotek in US
- Former Senior R&D Director at WuXi PharmaTech

Fang Liu
Government Affairs
Senior Director

- 19 years of experience in sales, government affairs, and market access
- Served in Double Crane Pharmaceutical and Yabao Pharmaceutical

Jian Cui
Regulatory Affairs
Senior Director

- Licensed Pharmacist
- 10 years of Eli Lilly and 10 years of AstraZeneca work experience in drug registration
- Experience in NDA/LE application and approval of more than 4 pharmaceutical products



Ying Guan (Helen)
Commercial Head

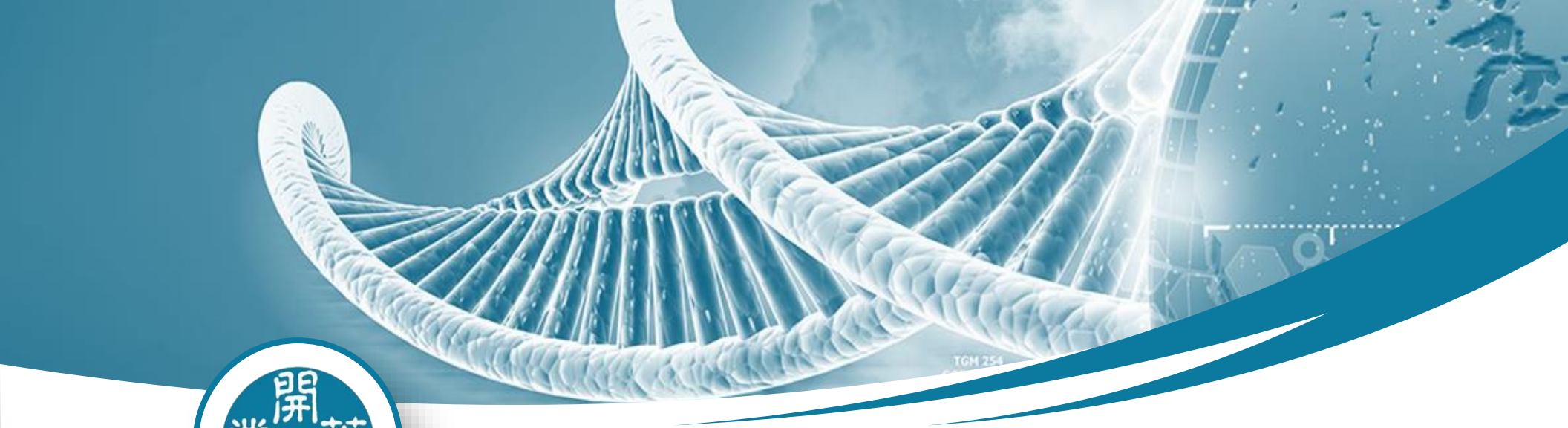
- 15 years of experience in marketing, new product launch, portfolio management
- Former Marketing Associate Director in Astrazeneca. Served in Tsumura, Santen, Baxter China

Enle Chen (Mark)
BD Director

- 10 years of experience in BD. Served in Bayer, Hanhui Pharmaceutical, and Springfield.
- Graduated from the Law School of Fudan University, passed China Bar Qualification, and was CFA Chart holder

Dr. Xue Zhong (Sandra)
BD Director

- More than 5 years of work experiences in R&D and BD
- Ph.D. from Changchun Institute of Applied Chemistry, Chinese Academy of Sciences
- Worked at HEC Research Center



Section 3

Our Strategies

Our Strategies

- *Rapidly advance the clinical development, regulatory approvals and commercial launch of proxalutamide in COVID-19*
- *Strategically progress the clinical development of proxalutamide in oncology therapies*
- *Continue the clinical development of pyrilutamide in both China and the United States*
- *Continue the clinical development of ALK-1 as a monotherapy and combination therapy and increase our focus on biologics R&D*
- *Enhance our proprietary R&D capabilities to further the development of potential first-in-class and best-in-class drugs, particularly based on our PROTAC technology platform*
- *Explore potential strategic partnerships with global pharmaceutical companies through licensing-in / licensing-out and co-development strategy*

R&D and Manufacturing Capabilities

Fully-integrated R&D Platform

Sophisticated R&D Process

Small-molecule + ***Biologics***

Pharmaco kinetics	***Chemistry***	***Biology***	***Antibody***
Clinical Operation	***Clinical Medicine***	***Formulation***	***Analytical Research***

Pre-clinical stage

Clinical stage

4,100m²
Total gross floor area globally

Experienced R&D Team

- *Our core R&D personnel includes leading scientists and researchers with drug discovery experience from U.S. biotech companies and global pharmaceutical companies*
- *Our core R&D personnel have accumulated extensive experience from research institutions, universities and pharmaceutical companies in the relevant therapeutic areas*
- *Majority of R&D personnel have obtained master's or Ph.D. degrees*

Global Supply Manufacturing Facility

Received production permit in Nov 2020

MAH *approval from NMPA*

First in China *for a novel drug developer*

20,000m²
Industrial land owned in Suzhou
Completed construction
Production permit ready in Nov **2020**

40,000 m²
Expected to be acquired for **APIs production**

50 million tablets per month (proxalutamide) capacity
expected in 2021 Q4

Section 4

Financial Performance

Income Statement

	Six months ended 30 June	
	2021	**2020**
RMB'000		
Revenues	**-**	**-**
Cost of sales	-	-
Gross profit	**-**	**-**
Other income	10,505	4,497
Marketing costs	(6,155)	(3,595)
Include: Share-based compensation expenses	(1,726)	(556)
Administrative expenses	(49,586)	(45,016)
Include: Listing expenses		(20,761)
Share-based compensation expenses	(9,114)	(3,894)
Research and development costs	(282,180)	(148,375)
Include: Share-based compensation expenses	(15,125)	(6,548)
Other (losses)/gains – net	3,015	(973)
Operating loss	**(324,401)**	**(193,462)**
Finance costs – net	(1,420)	(1,985)
Loss before income tax	**(325,821)**	**(195,447)**
Income tax expense	-	-
Loss and total comprehensive loss for the period	**(325,821)**	**(195,447)**
Less: One-time expenses and non cash items	25,965	31,759
Adjusted loss and total comprehensive loss for the period	**(299,856)**	**(163,688)**

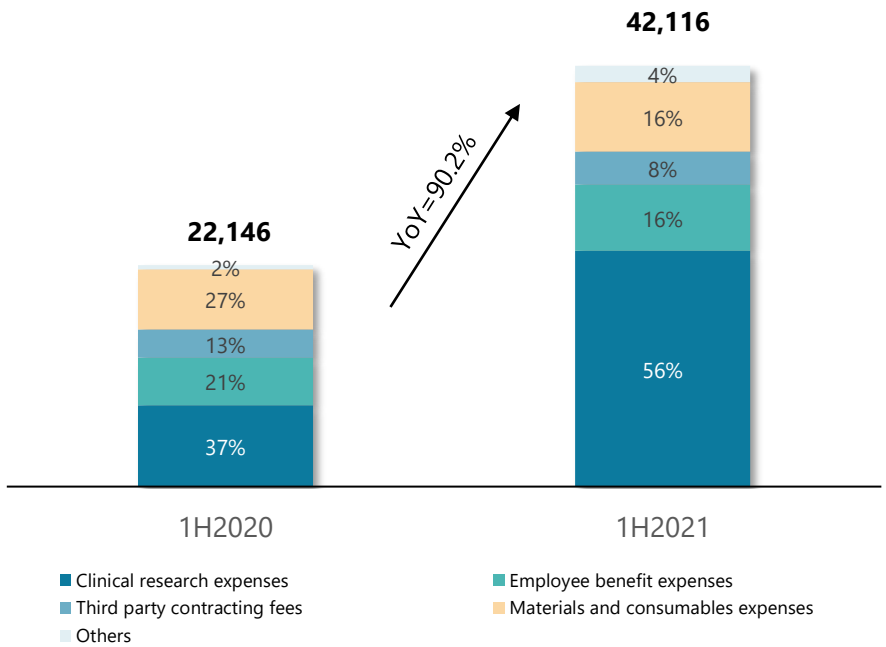
- *Exclude one-time expenses and non cash items (listing expenses and share-based compensation expenses)*
- *The share-based compensation expenses in 1H 2021 is RMB 26.0 million (USD 3.8 million); the listing expenses in 1H 2020 is RMB 20.8 million (USD 3.1 million), and the share-based compensation expenses is RMB 11.0 million (USD 1.6 million)*

Note: USD/CNY=6.7

Overview of Key Financials

Research and Development Cost

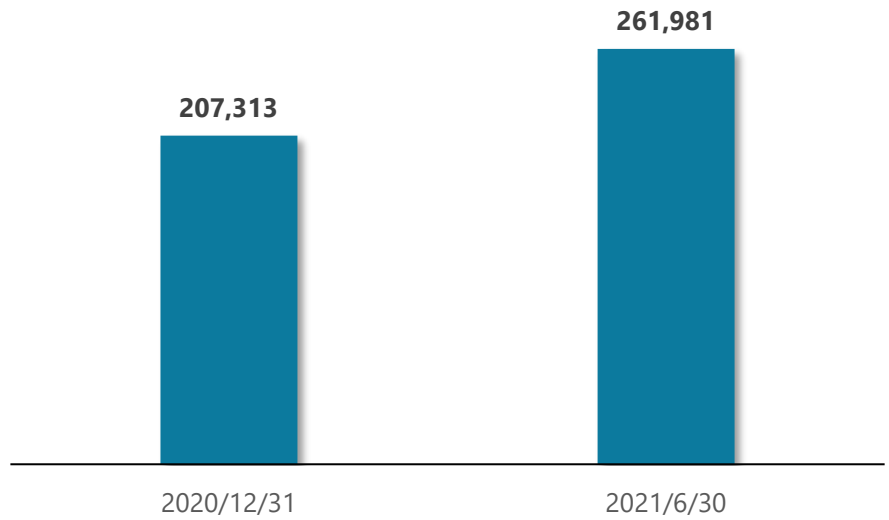
USD'000



- *R&D costs increased by 90.2% in 1H 2021: (i) an increase of RMB 103.6 million (USD 15.5 million) in clinical research expenses paid to hospitals; (ii) an increase of RMB 12.5 million (USD 1.9 million) in employee benefit expenses, including RMB 15.1 million (USD 2.3 million) in share-based compensation expenses; (iii) an increase of RMB 6.3 million (USD 0.9 million) in materials and consumables expenses; (iv) an increase of RMB 3.2 million (USD 0.5 million) in third-party contracting fees*

Cash and Cash Equivalents (incl. Time Deposits)

USD'000



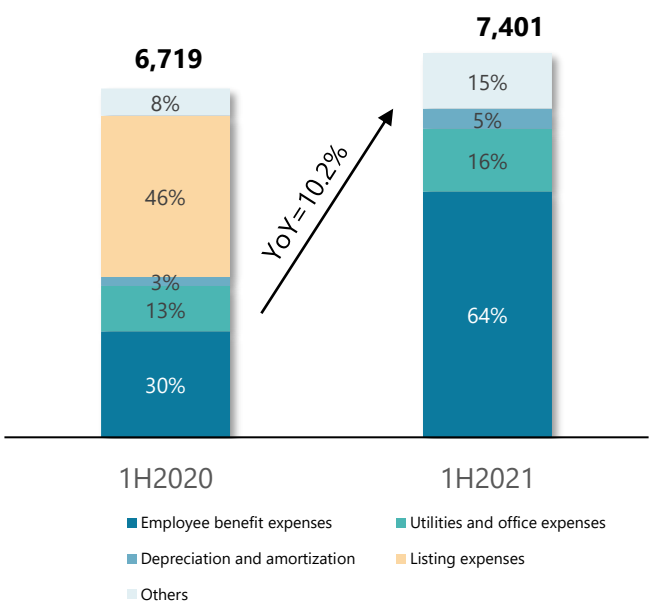
- *The company completed top-up placing in June 2021 with net proceeds of an amount of about HK $1.16billion (USD 150 million)*
- *As of 30 June 2021, we had utilized bank facilities of RMB 137.7 million (USD 20.6 million) and unutilized bank facilities of RMB 112.3 million (USD 16.8 million)*
- *The company has been listed in May 2020 with net proceeds of an amount of about HK $1.7billion (USD 221 million)*

Note: USD/CNY=6.7, USD/HKD=7.7

Overview of Key Financials

Administrative Expenses

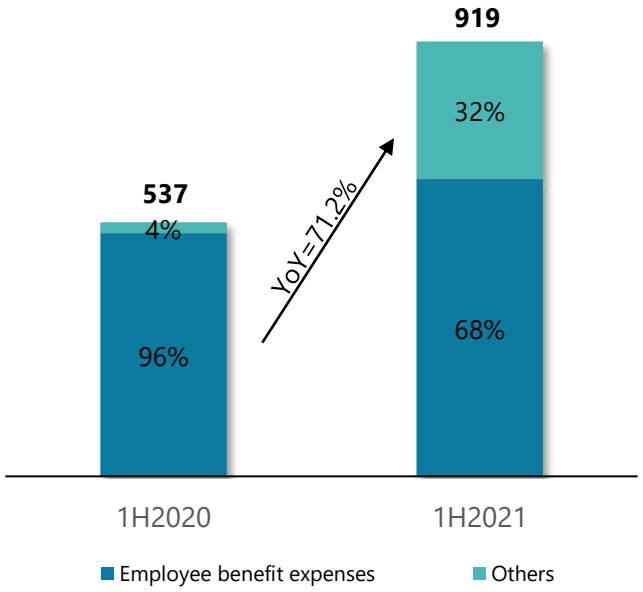
USD'000



- *The administrative expenses in 1H 2021 increased by 10.2% over the same period last year, mainly due to: (i) an increase of RMB 18.0 million (USD 2.7 million) in employee benefit expenses; (ii) an increase of RMB 2.2 million (USD 0.3 million) in utilities and office expenses as we expand office space; (iii) an decrease of RMB 20.8 million (USD 3.1 million) in listing expenses; and (iv) an increase of RMB 3.7 million (USD 0.6 million) in other administrative expenses*

Marketing Costs

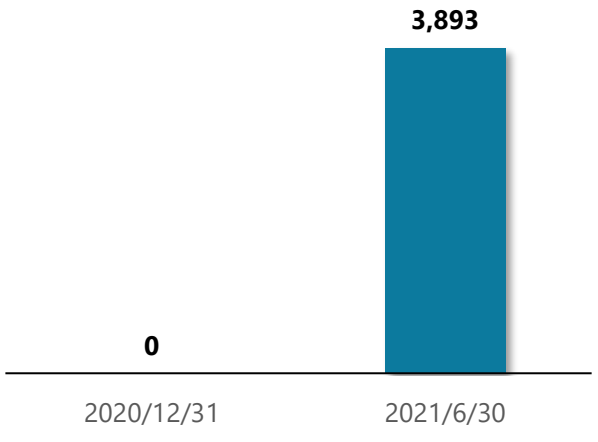
USD'000



- *Our marketing costs increased from RMB 3.6 million (USD 0.5 million) in 1H 2020 to RMB 6.2 million (USD 0.9 million) in 1H 2021, which consisted of the increase of employee benefit expenses by RMB 0.8 million (USD 0.2 million), mainly due to the establishment and expansion of sales and marketing team in preparation for the commercialization of proxalutamide*

Inventories

USD'000



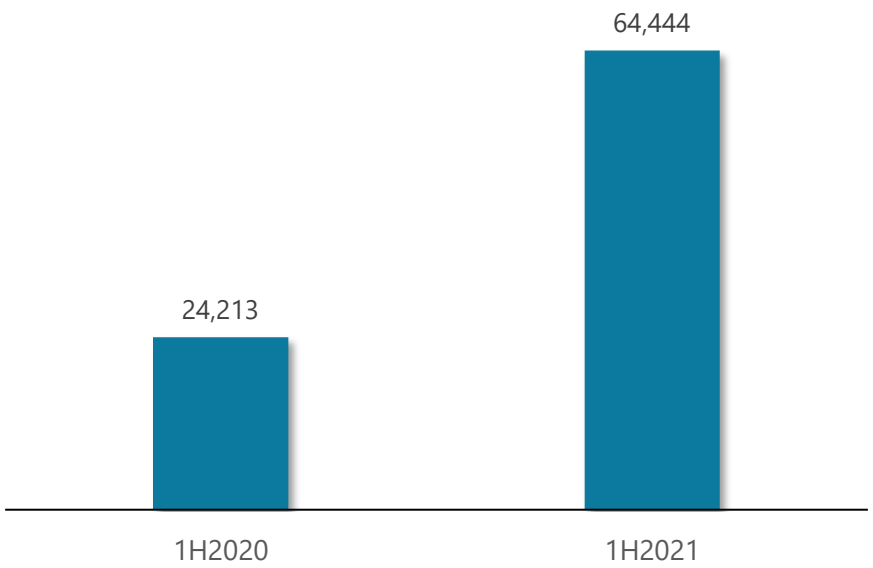
- *Our inventories increased from 0 in 2020 to RMB 26.1 million (USD 3.9 million) in 1H 2021, which is mainly due to preparation of materials for the commercialization of proxalutamide*

Note: USD/CNY=6.7

Overview of Key Financials

Net Cash Flows Used in Operating Activities

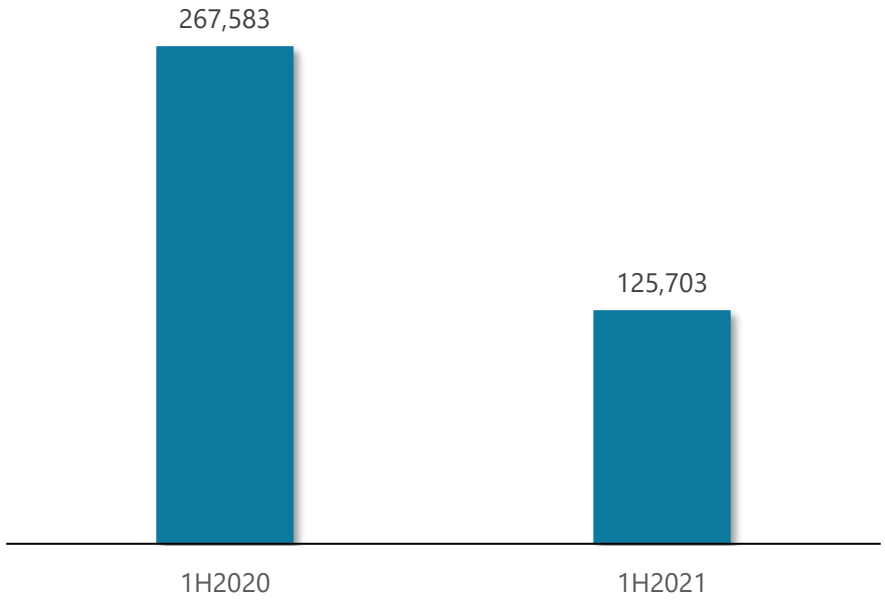
USD'000



- *The net cash outflow from operating activities mainly includes R&D expenses and administrative expenses*
- *In 1H 2021, the increase of R&D expenditure is mainly due to the increase of clinical research expenses and salary and welfare expenses brought by the expansion of R&D team size; the increase of administrative expenditure is mainly due to the increase of non R&D employees*

Net Cash Flows Generated from Financing Activities

USD'000



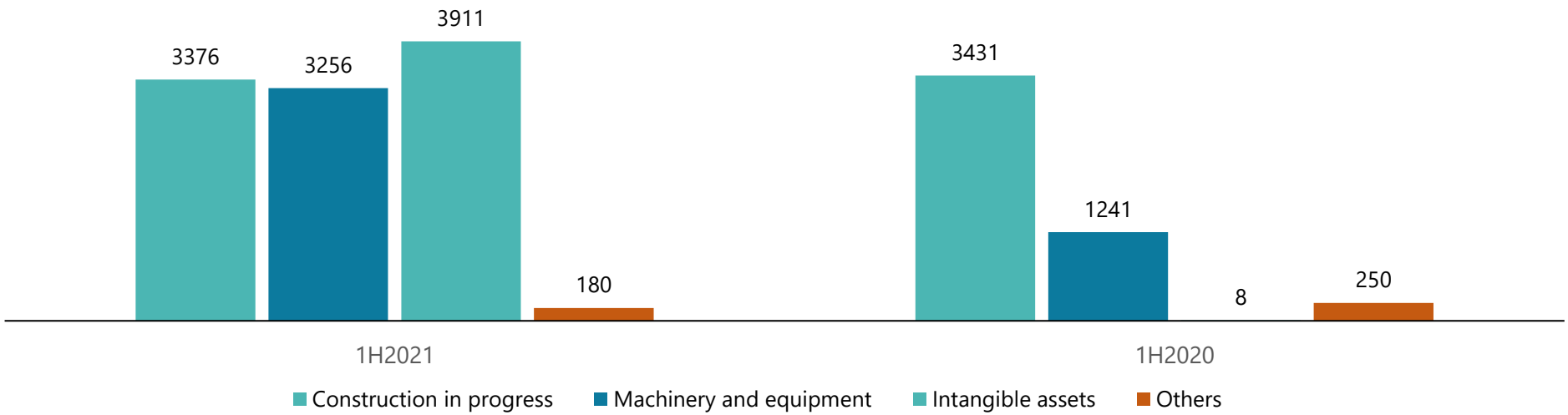
- *In 1H 2021, the net cash inflow from financing activities mainly includes proceeds of placing*
- *In 1H 2020, the net cash inflow from financing activities mainly includes IPO proceeds and bank borrowings*

Note: USD/CNY=6.7

Overview of Key Financials

Capital Expenditure

USD'000



- *In 1H 2021 and 1H 2020, our capital expenditure amounts are 71.8 million (USD 10.7 million) and RMB 33.0 million (USD 4.9 million) respectively, which are mainly used for upgrading of Suzhou factory for production capacity expansion, as well as land use rights expenses for Pinghu factory*
- *We expect capital expenditure in 2H 2021 and 2022 mainly to be design and engineering construction of the Pinghu factory, and lab equipment procurement of Guangdong Zhuhai R&D center*

Note: Intangible assets of 1H 2021 contains payment of land use rights, which is listed in lease liabilities (financing activities) in Cash Flow Statement

Note: USD/CNY=6.7

Income Statement

	Six months ended 30 June	
	2021	**2020**
RMB'000		
Revenues	**-**	**-**
Cost of sales	-	-
Gross profit	**-**	**-**
Other income	10,505	4,497
Marketing costs	(6,155)	(3,595)
Administrative expenses	(49,586)	(45,016)
Research and development costs	(282,180)	(148,375)
Other (losses)/gains – net	3,015	(973)
Operating loss	**(324,401)**	**(193,462)**
Finance costs – net	(1,420)	(1,985)
Loss before income tax	**(325,821)**	**(195,447)**
Income tax expense	-	-
Loss and total comprehensive loss for the period	**(325,821)**	**(195,447)**

- *In 1H 2021, our other income came from interest income and government subsidies, and our main expenditure was R&D and administrative expenses*
- *In the administrative expenses, employee benefit expenses increased significantly, while in R&D costs, clinical research expenses and employee benefit expenses increased significantly*
- *The COVID-19 trials of proxalutamide increase investment in 2021*
- *Other losses turns to other gains mainly due to foreign exchange gains*

Note: USD/CNY=6.7

Balance Sheet

	As of 30 Jun 2021 (Unaudited)	As of 31 Dec 2020 (Audited)
RMB'000		
Assets		
Non-current assets		
Property, plant and equipment	199,417	174,612
Intangible assets	209,679	209,760
Right-of-use assets	36,027	12,068
Other non-current assets	33,172	34,419
	478,295	430,859
Current assets		
Inventories	26,084	-
Other receivables, deposits and prepayments	141,269	31,621
Time deposits	522,406	323,407
Cash and cash equivalents	1,232,865	1,065,588
	1,922,624	1,420,616
Total assets	2,400,919	1,851,475
Liabilities		
Non-Current Liabilities		
Borrowings	132,100	134,900
Lease liabilities	-	490
Deferred income tax liabilities	38,818	38,818
	170,918	174,208

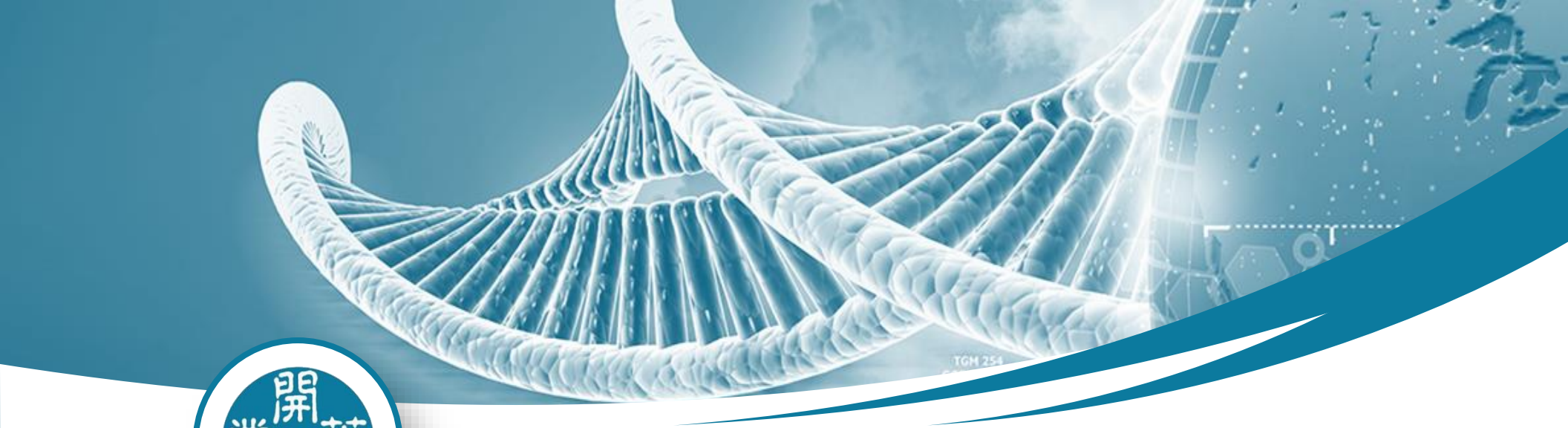
Balance Sheet

	As of 30 Jun 2021 (Unaudited)	As of 31 Dec 2020 (Audited)
RMB'000		
Current liabilities		
Trade and other payables	61,557	81,409
Borrowings	5,600	83,600
Lease liabilities	1,994	2,713
Deferred income	100	361
Amounts due to related parties	700	1,250
	69,951	169,333
Total liabilities	240,869	343,541
Equity		
Equity attributable to the equity holders of the company		
Share capital	273	261
Shares held for the Employee Incentive Scheme	(17)	(17)
Reserves	2,159,794	1,507,690
Total equity	2,160,050	1,507,934
Total equity and liabilities	2,400,919	1,851,475

Cash Flow Statement

	Six months ended 30 June	
	2021	**2020**
RMB'000		
Net cash used in operating activities	(431,776)	(162,225)
Net cash (used in)/generated from investing activities	(243,785)	(33,032)
Net cash generated from financing activities	842,207	1,792,803
Net increase/(decrease) in cash and cash equivalents	**166,646**	**1,597,546**
Cash and cash equivalents at the beginning of the period	1,065,588	195,532
Exchange gains on cash and cash equivalents	(255)	(919)
Cash and cash equivalents at the end of the period	**1,231,979**	**1,792,159**

Q&A



Appendix A

Results of Clinical Trials

1 Proxalutamide's Phase II Clinical Trials of mCRPC in China

Protocol of Clinical Trials

Cohorts: *108 patients with 3 dose groups: 100 mg(37), 200 mg(35), 300 mg(36)*

Inclusion Criteria: *mCRPC patients who had failed standard chemotherapy regimen containing Docetaxel or were unable to tolerate or unwilling to receive standard chemotherapy treatment*

	100 mg ***N=37***	*200 mg* ***N=35***	*300 mg* ***N=36***	*Total* ***N=108***
Post-Chemo	*10 (27.0%)*	*13 (37.1%)*	*15 (41.7%)*	*38 (35.2%)*
Docetaxel	*8 (21.6%)*	*12 (34.3%)*	*12 (33.3%)*	*32 (29.6%)*
Other Chemo	*4 (10.8%)*	*6 (17.1%)*	*5 (13.9%)*	*15 (13.9%)*

Principle Entity of Investigation: *Shanghai Changhai Hospital*

Dosing Duration: *Received oral proxalutamide tablets until six treatment cycles(28 days per treatment cycle), or unable to tolerate*

Primary Endpoint: *maximum PSA decline rate*

Safety Comparison with Enza and Abi

	Proxaluta-mide Ph. II[1]	COU-AA-301[2] （Abiraterone post-chemo）	COU-AA-302[3]（Abi prior-chemo）	AFFIRM[4]（Enzaluta-mide post-chemo）
≥grade 3 AE	25.9%	60.4%	47.6%	45.3%
Drug related≥ grade 3 AE	13.0%	23.0%	22.5%	/
SAE	15.7%	42.4%	32.8%	33.5%
Drug related SAE	4.6%	11.1%	10.9%	/
Withdraw	5.6%	20.5%	10.1%	7.6%
Drug related withdraw	2.8%	5.4%	5.4%	/
Death	1.9%	13.3%	3.7%	2.9%
Drug related Death	0	1.0%	0.9%	/
Seizure	0	0	0	0.9%[5]

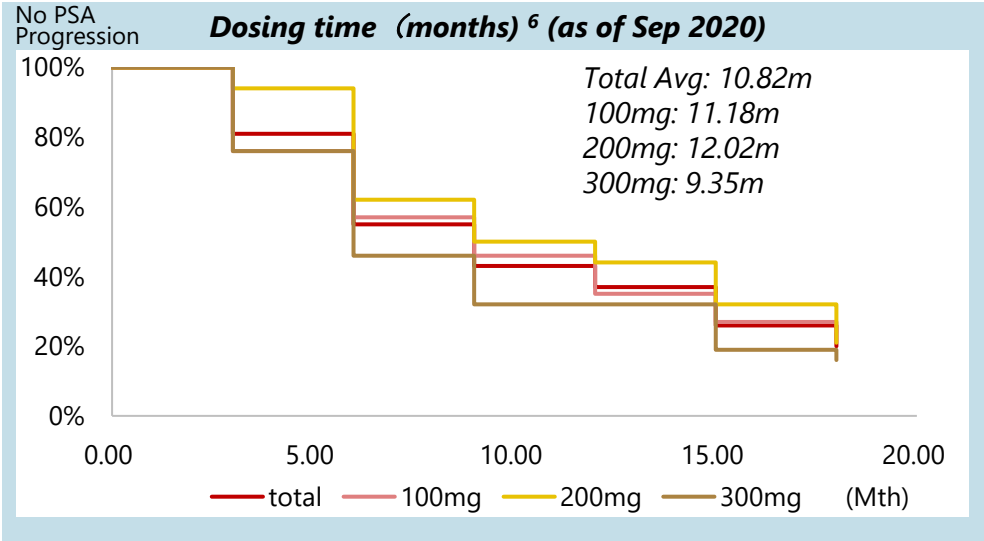
Source: EMA assessment report EMEA/H/C/002321/II/0004/G, EMAassessment report EMEA/H/C/002639
Note: 1. CDE Identifier: CTR20170177 2. Clinical Trials Identifier: NCT00638690 3. NCT00887198 4. NCT00974311 5. 0.9% in this assessment report, and 0.5% for Xtandi overall (labeling dated Dec 2019)

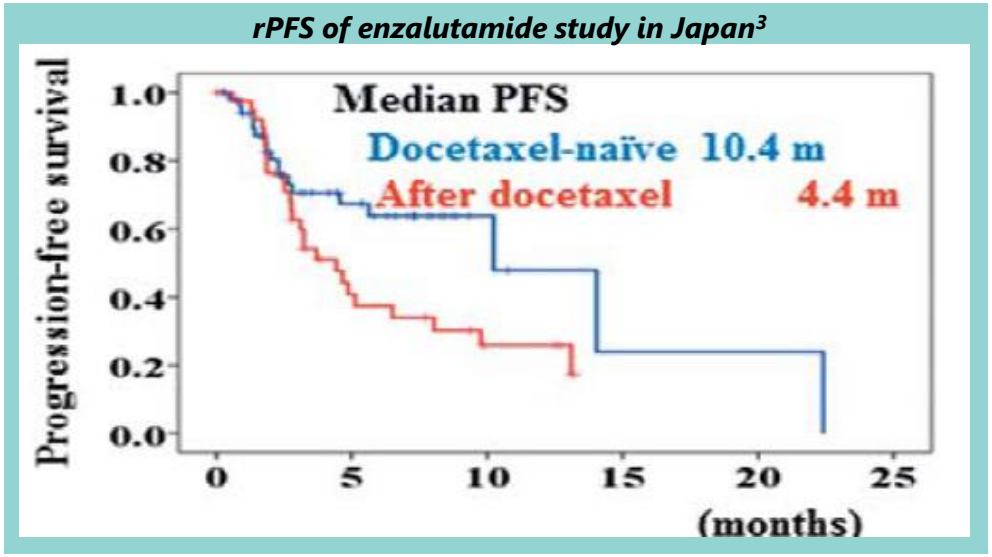
1 Proxalutamide's Phase II Clinical Trials of mCRPC in China

Efficacy Comparison with Enza and Abi

Drug	Location	PSA_{50}	ORR/ SD[4]	Ph	Safety
Proxalutamide	China	41.9%	ORR 15.8%; SD 63.2%	II	≥Grade 3 AEs, 25.9%, of which 13% was drug related
Abiraterone	Japan[1]	28.3%	ORR 4.5%; SD 40.9%	II	≥Grade 3 AEs, 40.4%
	Gobal[2]	29%	ORR 14%	III	Serious AEs, 46.14%
Enzalutamide	Japan[3]	43.6%	-	NA[8]	≥Grade 3 AEs, 1%[5]
	Japan[7]	28.9%	ORR 5.3%; SD 42.1%	II	Serious AEs, 34.2%

- A retrospective study in Japan has found that, rPFS of post-chemo mCRPC patients taking enzalutamide was **4.4 mth** (right lower panel)
- For enzalutamide Phase III clinical trial for patients with docetaxel-naïve in Asia, TTPP was **8.3 mth** (TTPP was **5.55 mth** and rPFS was **9.43 mth** for China group)
- For proxalutamide Phase II clinical trial in China for mCRPC patients post chemo or chemo intolerant, the average dosing time (dosing duration) for 200mg cohort per day has been **12.02** mth as of Sep, 2020 (right upper panel)
- 200mg corhort was chosen for proxalutamide's as a monotherapy of ongoing Phase III trial in China.





Note: 1. NCT01795703; 2. NCT00638690; 3. Retrospective study by Cancer Institute Hospital, Japan; 4. Based on RECIST; 5. No Seisure but a syncope. Xtandi seizure rate 0.5%; 6. Dosing duration reflects progression free survival time; 7. NCT01284920; 8. From paitens treated during 2014-2015 in Cancer Institute Hospital

1 Conclusion of Proxalutamide Phase II Clinical Trials in China

✓ *Proxalutamide(41.9%) showed better PSA50 effect than Abiraterone global[2] (29%) and Abiraterone Japan[1](29%);*

✓ *As of September 2020, the PSA50 rate in 100 mg dose group of proxalutamide was slightly lower (35.1%), the PSA50 rate of the 200 mg and 300 mg dose groups reached 45.5% and 45.7%, respectively, which was better than the results of enzalutamide in Japan[3] (43.6%);*

✓ *As of September 2020, the dosing duration (reflects progression free survival time) of proxalutamide reached 10.82 m (100 mg group: 11.18 m; 200 mg group: 12.02 m; 300 mg group: 9.35 m). In addition, There were 10 patients in the donated period, which would further extend the average dosing duration;*

✓ *As of September 2020, the ratio of more than 15m and 18m dosing duration in the 200 mg cohort exceeded 31.4% and 20%, respectively, which was far better than Japan's enzalutamide trial[3](20% for non-chemotherapy patients);*

✓ *The safety of proxalutamide was much better than that of Abiraterone, and there was no seizure with proxalutamide(the Seizure rate of enzalutamide is 0.5%[4]).*

Note: 1. NCT01795703; 2. NCT00638690; 3.Retrospective study by Cancer Institute Hospital, Japan; 4. Xtandi label

1 Proxalutamide Phase I/Ib Clinical Trials of mBC in China

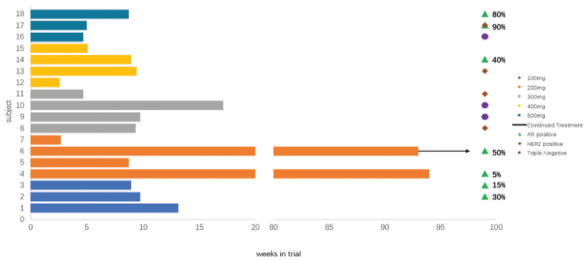
Phase I/Ib Clinical Trials in China

To evaluate the safety, pharmacokinetics and pharmacodynamics of Proxalutamide with single and multiple dosage applications , overall efficacy of the drug and to determine the recommended dose for phase III clinical trials

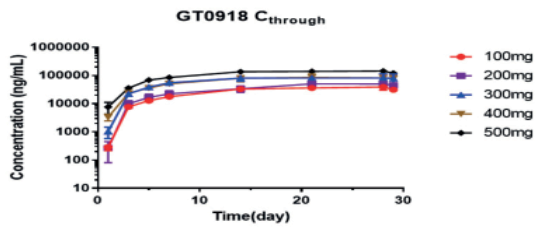
Phase I Clinical Results

Showed Proxalutamide was well-tolerated and could provide better clinical outcomes for patients with the AR+ biomarker

Treatment cycles of patients of various dosages



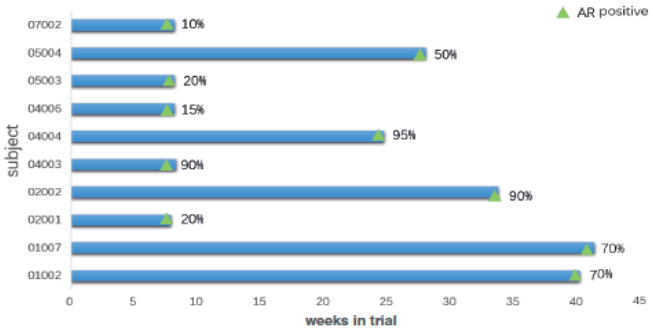
Plasma concentration levels vs. dosage levels



Phase Ib Clinical Results

5/13 patients were treated with more than 6 treatment cycles of 28 days, showing that Proxalutamide has therapeutic effect on advanced metastatic AR+TNBC

Treatment cycles of TNBC patients in 200 mg dose group



- *30 patients in the 200 mg dose group (12 with AR+TNBC, 15 with AR+HR+ and 3 with AR+HER2+)*
- *15 patients in the 300 mg/day dose group (2 with AR+TNBC, 9 with AR+HR+, and 4 with AR+HER2+)*
- *All patients had advanced AR+ metastatic breast cancer and previously experienced at least 2 lines of treatments*

Safety

No DLT was observed and MTD was not reached; Proxalutamide-related AEs were all Grade 1 or 2

Efficacy

5/13 patients in the 1b trials were treated with more than 6 treatment cycles

Appendix B

Results of COVID-19 IIT in Brazil

1 Proxalutamide for COVID-19 Outpatients in Brazil

*In July 2020, **Kintor** and **Applied Biology** entered into a clinical trial research agreement to conduct research for proxalutamide (GT0918) as a treatment for the novel coronavirus disease (COVID-19). Applied Biology is a biotechnology company committed to the development of breakthrough drugs and medical devices for the treatment of androgen and hair disorders.*

ClinicalTrials.gov identifier: NCT04446429

Protocol

(Randomized, Double-blind, Placebo-controlled)

Inclusion Criteria:

Male (18-year or older) and female (post-menopause) patients with mild to moderate COVID-19. Symptom severity ranges from 1 to 2 point as assessed by the WHO COVID-19 ordinal scale.

Arms and Interventions:

- ☐ *Male cohort with patients randomized in a 1:1 ratio in Experimental arm and control arm*
- ☐ *Female cohort with with patients randomized in a 1:1 ratio in Experimental arm and control arm*
- *Experimental arm: Proxalutamide + Standard Care*

  Control arm: Standard Care (Ivermectin + Azythromycin)

Primary end point:

The co-primary endpoints of the clinical trial are the percentage of subjects hospitalized with COVID-19 and the COVID-19 Ordinal Outcome Scale (a 8-point ordinal scale published by the World Health Organization, such as mechanical ventilation usage and death) in 30 days.

Status

- ☐ *On Aug 20, 2020, the first male patient was enrolled*
- ☐ *On Oct 25, 2020, completed initial target 254 male patients enrolment*
- ☐ *On Nov 30, 2020, launched enrolment of 168 female patients as suggested by MoH of Brazil*
- ☐ *On Jan 7, 2021, published updated data of male patients.*
- ☐ *On Jan 10, 2021, published preliminary data of female patients.*

COVID-19 Ordinal Outcome Scale: 1. Not hospitalized, no limitations on activities; 2. Not hospitalized, limitation on activities; 3. Hospitalized, not requiring supplemental oxygen - no longer requiring ongoing medical care; 4. Hospitalized, not requiring supplemental oxygen- requiring ongoing medical care (COVID-19 related or otherwise); 5. Hospitalized, requiring supplemental oxygen; 6. Hospitalized, on non-invasive ventilation or high flow oxygen devices; 7. Hospitalized, on invasive mechanical ventilation or ECMO; 8. Death.

1 Baseline of Male Patients and Ordinal Scale after Treatment

Baseline

	Proxalutamide arm (n = 134)	Control arm (n = 134)
Age *Median*	45	46
No. of coexisting conditions —no.(%)		
None	74 (55)	84 (63)
One	29 (22)	20 (15)
Two or more	31 (23)	24 (18)
Coexisting conditions — no. (%)		
Type 2 diabetes	11 (8)	10 (7)
Hypertension	33 (25)	22 (16)
COPD	1 (0.7)	0 (0)
Obesity	22 (16)	21 (16)
Ordinal scale of baseline		
1	63 (47)	97 (72)
2	71 (53)	37 (28)

Day 30 ordinal scale

	Proxalutamide arm (n = 134)	Control arm (n = 134)
1: *Not hospitalized, no limitations on activities*	132 (99)	104 (78)
2: *Not hospitalized, limitation on activities*	2 (1)	17 (13)
3: *Hospitalized, not requiring supplemental oxygen - no longer requiring ongoing medical care*	0 (0)	0 (0)
4: *Hospitalized, not requiring supplemental oxygen-requiring ongoing medical care (COVID-19 related or otherwise)*	0 (0)	4 (3)
5: *Hospitalized, requiring supplemental oxygen*	0 (0)	4 (3)
6: *Hospitalized, on non-invasive ventilation or high flow oxygen devices*	0 (0)	0 (0)
7: *Hospitalized, on invasive mechanical ventilation or ECMO*	0 (0)	3 (2)
8: *Death.*	0 (0)	2 (1)

Source: John McCoy, Andy Goren, Flavio Adsuara Cadegiani et al., 17 June 2021, https://doi.org/10.21203/rs.3.rs-135303/v2

1 Efficacy Results of Proxalutamide COVID-19 Trial in Outpatients

The final results of 268 male patients showed that the trial met primary endpoint on Day 30

	Proxalutamide arm (n=134)		Control arm (n=134)	
	Cases	Percentage	Cases	Percentage
Hospitalization	3	2%	35	26%
Supplemental oxygen	2	1%	33	25%
Non-invasive ventilation	0	0%	19	14%
High flow oxygen devices	1	1%	26	19%
Invasive mechanical ventilation	0	0%	17	13%
ECMO	0	0%	6	4%
Vasopressors	0	0%	12	9%
Death	0	0%	2	1%

The preliminary analysis of female patients as of Jan 7, 2021 was based on 60 patients in proxalutamide arm and 35 patients in the control arm

	Proxalutamide arm (n=60)		Control arm (n=35)	
	Cases	Percentage	Cases	Percentage
Hospitalization	*1*	*1.7%*	*6*	*17.1%*
Admission to ICU	*0*	*0%*	*3*	*8.6%*
Mechanical ventilation requirement	*0*	*0%*	*2*	*5.7%*
Death	*0*	*0%*	*1*	*2.9%*

Source: John McCoy, Andy Goren, Flavio Adsuara Cadegiani et al., 17 June 2021, https://doi.org/10.21203/rs.3.rs-135303/v2

1 The Analysis for SARS-CoV-2 rt-PCR Test Results

- **The rate of negative rt-PCR test for SARS-CoV-2 at D7 with treatment of proxalutamide compared with Control:**

Gender	No. of Subjects Analyzed Proxa. vs control）	Proxalutamide		Control		Relative Rate of negative rt-PCR test Compared with Control (95%CI)	P Value
		n	Rate (%)	n	Rate (%)		
Male	100 vs 28	**81**	**81%**	6	21%	**60%** (39.9 – 72.8%)	< 0.0001
Female	71 vs 37	**60**	**85%**	14	38%	**47%** (28% - 62.3%)	< 0.0001
Male & Female	171 vs 65	**141**	**82%**	20	31%	**51%** (42.5 – 66.8%)	< 0.0001

Proxalutamide can significantly speed up the clearance process of the virus from COVID-19 patients:

The relative rate of negative rt-PCR test at day 7 were 51%.

*(Negative rate in Proxalutamide was **82%,** versus **31%** in Control group)*

Source: Cadegiani et al. Cureus 13(2): e13492. DOI: 10.7759/cureus.

1 Safety Results of Proxalutamide COVID-19 Trial in Outpatients

■ Summary of treatment-emergent adverse events (TEAE)

Type of AEs	Proxalutamide (N = 134)		Control (N = 128)	
	n	%	n	%
Fatigue	1	1%	71	55%
Fever	2	1%	34	27%
Disease progression	4	3%	43	34%
Hy	3	2%	36	28%
Dehydration	20	15%	51	39%
Increase in ALT or AST	4	3%	22	17%
Shortness of breath	4	3%	40	31%
Gastrointestinal				
Diarrhea	39	28%	20	16%
Nausea	21	16%	15	12%
Abdominal pain	22	16%	18	14%
Vomiting	4	3.0%	6	5%
Dyspepsia or heartburn	23	17%	6	5%
Cardiac				
Tachycardia	6	4%	45	35%
Nervous System				
Headache	1	1%	12	9%
Ageusia	13	10%	23	18%
Diffuse sweating	48	36%	5	4%
Orthostatic dizziness	6	4%	8	6%
Anosmia	14	10%	26	20%
Skin and subcutaneous tissue				
Skin Lesions	10	7%	7	5%
Musculoskeletal and Connective Tissue				
Arthralgia	5	4%	22	17%
Muscle pain	3	2%	39	30%
Lower back pain	11	8%	24	19%
Upper back pain	5	4%	12	9%
Pain in Extremity	2	1%	4	3%
Total TEAEs*	**276**	-	**591**	-

** A patient with multiple adverse events was counted more than once in the total row.*

◆ **Conclusion: compared with control arm, proxalutamide arm shows good safety**

a) TEAEs were reported for 61.2% of subjects in the proxalutamide group and for 90.6% of subjects in the control group;

b) The most frequently reported TEAEs (occurring in ≥10% of subjects) included dehydration, diarrhea, Nausea, Abdominal pain, and dyspepsia;

c) Gastrointestinal AEs were suspected treatment-related AEs.

2 Proxalutamide for COVID-19 Inpatients in Brazil

ClinicalTrials.gov identifier: NCT04728802

- ***In Jan 2021, was accepted for accelerated review by the Institutional Review Board ("IRB") of Brazil.***

Protocol

(double-blinded, randomized and multi-center investigational study)

Inclusion Criteria:

Hospitalized COVID-19 male and female patients of 18 years old or above. Symptom severity ranges from 3 to 6 point as assessed by the WHO COVID-19 ordinal scale.

Arms and Interventions:

- *645 patients (366 male and 279 female) .*
- *The patients were randomized at a ratio of 1:1 to Proxalutamide Arm (317 patients) and Control Arm (328 patients), respectively.*

Primary endpoint:

Treatment efficacy of Proxalutamide arm relative to the Control arm as assessed by the WHO COVID-19 ordinal scale on day 14.

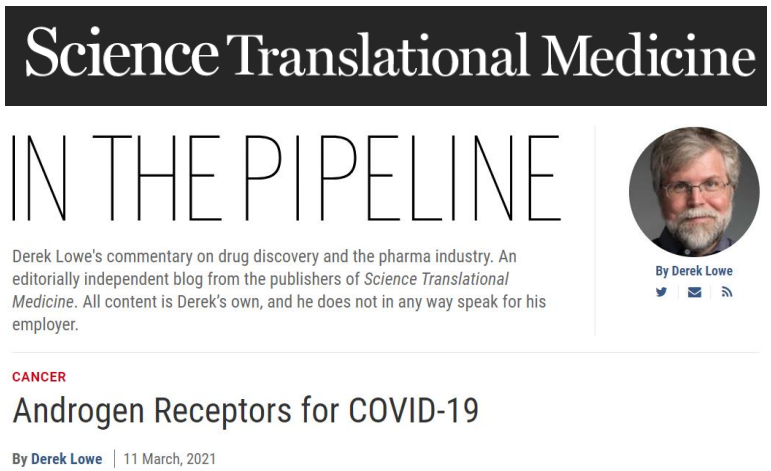
- ***On Feb 2, 2021, commenced patients enrollment in 12 sites in Amazonas. On Feb 21, completed patients enrolment. On Mar 10, announced preliminary analysis.***

Study points out that the drug Proxalutamide may be effective against Covid-19 and its variants

The study focused on the drug Proxalutamide was carried out by the Samel Group and Applied Biology. know more

By João Paulo Castro

Posted on 10/03/21 at 18h03



Science Translational Medicine

IN THE PIPELINE

Derek Lowe's commentary on drug discovery and the pharma industry. An editorially independent blog from the publishers of *Science Translational Medicine*. All content is Derek's own, and he does not in any way speak for his employer.

By Derek Lowe

CANCER

Androgen Receptors for COVID-19

By Derek Lowe | 11 March, 2021

Source: https://www.portaltucuma.com.br/estudo-aponta-que-o-medicamento-proxalutamida-pode-ser-eficaz-contra-a-covid-19-e-suas-variantes/
https://blogs.sciencemag.org/pipeline/archives/2021/03/11/androgen-receptors-for-covid-19

2 Baseline of Proxalutamide COVID-19 Trial for Inpatients

		Proxalutamide arm (n=317)	Control arm (n=328)
Age *Median*		*50*	*49*
Sex *No. (%)*			
	Female	*133 (42.0)*	*146 (44.5)*
	Male	*184 (58.0)*	*182 (55.5)*
COVID-19 ordinal scale *No. (%)*			
	Score 3	*0 (0.0)*	*2 (0.6)*
	Score 4	*7 (2.2)*	*11 (3.3)*
	Score 5	*93 (29.3)*	*103 (31.4)*
	Score 6	*217 (68.5)*	*212 (64.6)*

Note: Intention-to-treat analysis (ITT)
Source: https://www.medrxiv.org/content/10.1101/2021.06.22.21259318v1

2 Results of Proxalutamide COVID-19 Trial for Inpatients (Efficacy)

Based on 317 patients (58% male) in the proxalutamide arm and 328 patients (55.5% male) in the control arm, the primary endpoint was met on Day 14 and proxalutamide increased recovery[1] rate by *128%*

	Proxalutamide arm (n=317)	Control arm (n=328)
COVID-19 ordinal scale *No. (%)*	1	7
Recovery rate *No. (%)*	258 (81.4)	117 (35.7)
Female	109 (82.0)	51 (34.9)
Male	149 (81.0)	66 (36.3)
Mortality rate *No. (%)*	27 (8.5)	130 (39.6)

The results on Day 28 showed that proxalutamide reduced mortality risk by *78%*, and shortened median time to recover by *5 days*

	Proxalutamide arm (n=317)	Control arm (n=328)
Recovery rate *No. (%)*	271 (85.5)	155 (47.3)
Mortality rate *No. (%)*	35 (11.0)	162 (49.4)[2]
Time to recover / alive hospital discharge *Median*	5-day	10-day

Note: 1. Recovery means alive hospital discharge [scores 1, 2]; 2. According to The Lancet, a 50% (n = 13,496) mortality rate was reported for in-hospital mortality in North Brazil (Amazonas).https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30560-9/fulltext

Source: https://www.medrxiv.org/content/10.1101/2021.06.22.21259318v1

2 Results of Proxalutamide COVID-19 Trial for Inpatients (Safety)

Characteristic	Overall N=645	Proxalutamide N=317	Placebo N=328	P
Grades 4 or 3 – n (%)				
Shock, requiring vasopressors	141 (21.9)	7 (2.2)	134 (40.9)	<0.001
Renal failure (creatinine increase > 100%)	26 (4.0)	5 (1.6)	21 (6.4)	0.29
Females	12 (4.3)	1 (0.7)	11 (7.5)	0.33
Males	14 (3.8)	4 (2.2)	10 (5.4)	0.58
Liver damage (ALT > 250 U/L or >100% increase)	23 (3.6)	4 (1.3)	19 (5.8)	0.32
Females	10 (3.6)	0 (0.0)	10 (6.8)	0.37
Males	13 (3.6)	4 (2.2)	9 (4.9)	0.65
Grades 2 or 1 – n (%)				
Diarrhea	63 (9.8)	51 (16.1)	11 (3.3)	0.005
Females	29 (10.4)	22 (16.5)	7 (4.8)	0.091
Males	31 (8.5)	29 (15.9)	4 (1.1)	0.025
Abdominal pain	4 (0.6)	3 (0.9)	1 (0.3)	0.89
Females	1 (0.4)	1 (0.7)	0 (0.0)	0.91
Males	3 (0.8)	2 (1.1)	1 (0.5)	0.93
Irritability	4 (0.6)	4 (1.3)	0 (0.0)	0.78
Females	1 (0.4)	1 (0.7)	0 (0.0)	0.91
Males	3 (0.8)	3 (1.6)	0 (0.0)	0.79
Spontaneous erection				
Males	4 (1.1)	4 (2.2)	0 (0.0)	0.73
Vomiting, dyspepsia, or palpitations	0 (0.0)	0 (0.0)	0 (0.0)	1

Source: https://www.medrxiv.org/content/10.1101/2021.06.22.21259318v1

Appendix C

Results of COVID-19 IIT in Brazil

1 Spread of SARS-CoV-2 Gamma (P.1) Variant Globally

March 18th,2021

Country	Confirmed cases
Brazil	362
Italy	153
Belgium	47
USA	39
Peru	23
Germany	22
Switzerland	18
Colombia	14
United Kingdom	12
France	11
Portugal	10
Japan	6
Ireland	6
Sweden	6
The Netherlands	5
French Guiana	4

May 17th, 2021

Country	Confirmed cases
Canada	9129
USA	8048
Brazil	3677
Italy	743
Belgium	685
Spain	304
The Netherlands	296
Chile	245
France	196
Germany	181
Turkey	166
United Kingdom	113
Peru	103
Portugal	100
Switzerland	69
French Guiana	68

June 1st, 2021

Country	Confirmed cases
United States	11220
Canada	9730
Brazil	6132
Belgium	882
Italy	838
Spain	421
Netherlands	356
Chile	249
Argentina	238
Germany	226
France	222
Turkey	166
Colombia	147
United Kingdom	143
Mexico	124

August 9th, 2021

Country	Confirmed cases
USA	23,373
Brazil	16,200
Canada	8,070
Belgium	1,974
Mexico	2,278
Chile	2,522
Spain	957
Italy	2,181
Netherlands	566
Colombia	346
Germany	806
France	577
Trinidad and Tobago	255
Argentina	329
French Guiana	318
World (71 countries)	Total: **63,769**

Note: Top 15 countries were listed
Source: GISAID

2 Spread of SARS-CoV-2 Delta Variant Globally

May 27th,2021

Country	Confirmed cases (GISAID)[4] as of 27 May
United Kingdom	7338
India	3203
USA	1326
Germany	334
Canada	163
Japan	157
Singapore	156
Ireland	154
Australia	130
Denmark	105
Belgium	91
France	66
Italy	65
Spain	60
Switzerland	54

June 10th,2021

Country	Confirmed Delta variant cases: (PANGOLIN)[55] as of 10 June
United Kingdom	20931
India	3220
United States	1760
Singapore	234
Belgium	189
Russia	161
Spain	152
Japan	147
Italy	144
Australia	131
Ireland	128
Thailand	92
Denmark	90
France	87
Switzerland	73

June 24th,2021

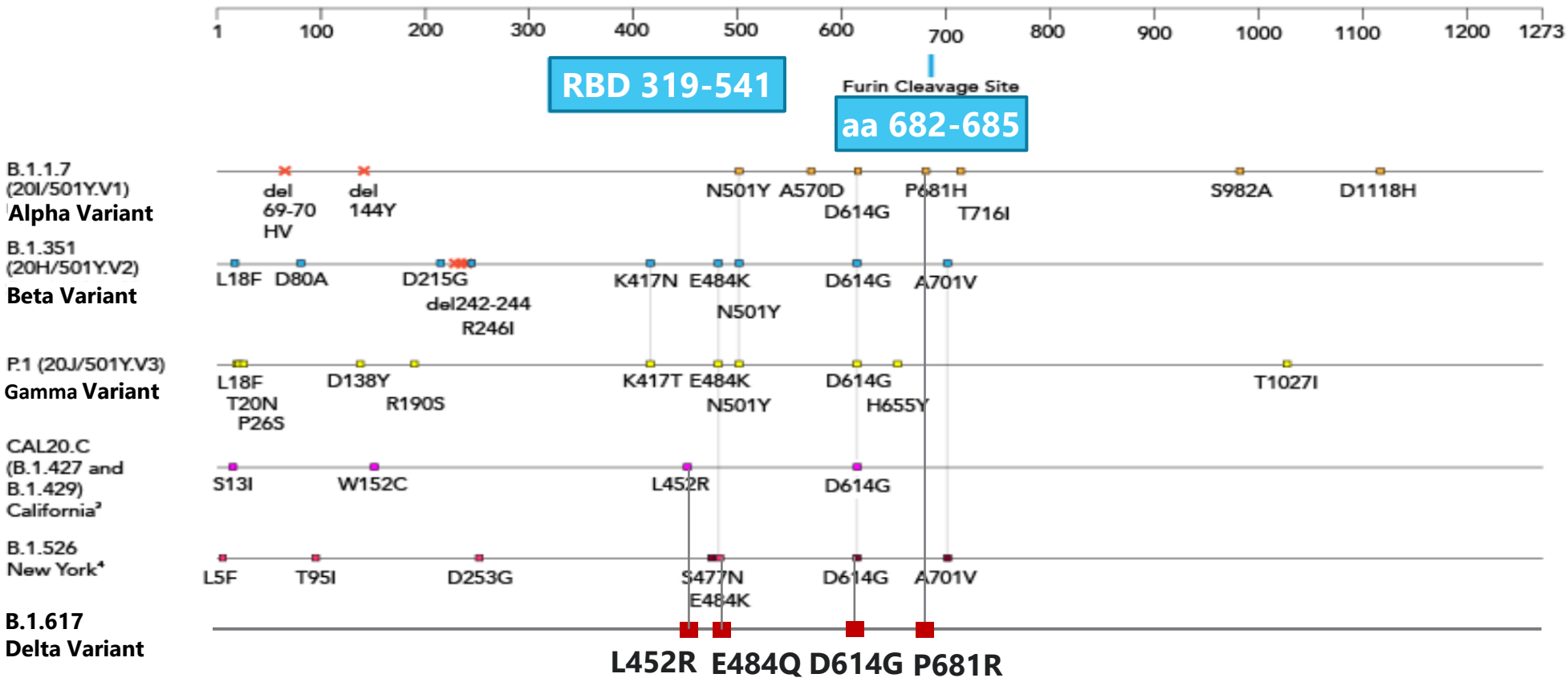
Country/Area	Confirmed Delta variant cases: (PANGOLIN)[58] as of 24 June
United Kingdom	51 349
India	5,694
United States	3 234
Germany	1 274
Singapore	823
Spain	423
Belgium	357
Russia	284
Japan	196
Italy	190
Australia	171
Portugal	151
Ireland	144
France	119
Switzerland	114

August 18th,2021

Country/Area	Confirmed Delta variant cases: (PANGOLIN)[115] as of 18 August
United Kingdom	239,594
United States	86,350
Denmark	23,365
India	15,693
France	10,063
Germany	9,252
Italy	8,027
The Netherlands	7,886
Spain	6,443
Sweden	5,587
Turkey	5,489
Switzerland	5,150
Belgium	4,942
Ireland	4,461
Portugal	4,151
World (130 countries)	Total: **460,419** (solely B.1.617.2)

Note: Top 15 countries were listed
Source: GISAID, outbreak.info, PANGOLIN

Amino Acid Changes in the Spike (S) Protein in SARS-CoV-2 Variants



Source: American Society for Microbiology