1H22 Interim Results Presentation

August 2022

嘉和 GENOR BIOPHARMA

股票代码:6998.HK

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Agenda

1 Business Review

2 Pipeline Introduction

3 Upcoming Milestones

4 Financial Overview

01

Business Review

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Business Highlights – 1H2022

- **Operation efficiency – Focus, Restructure, Optimization**
  - Focus on priorities
  - Reduce non-essential expenses
  - Adopt multiple initiatives to improve efficiency

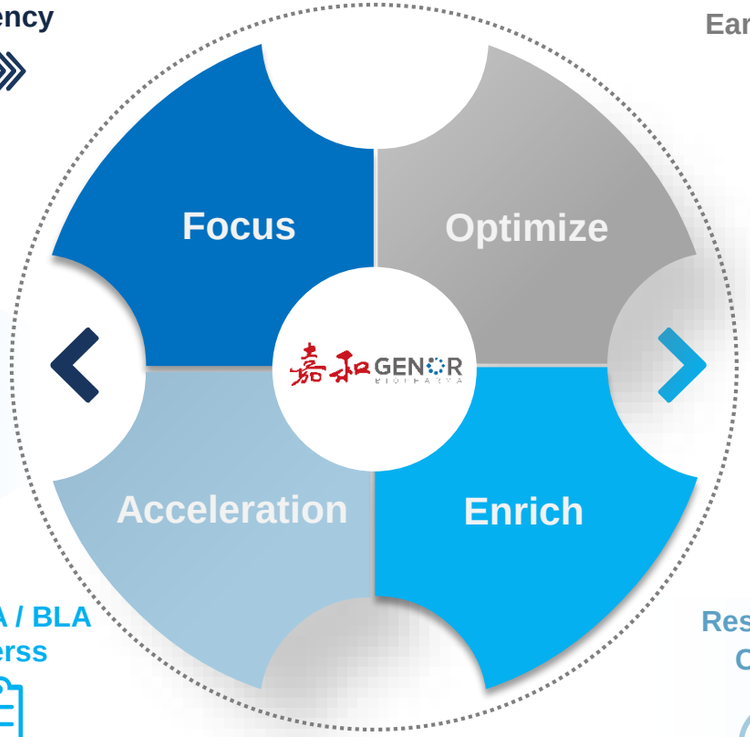
- **GB261 achieved preliminary clinical POC data**
- **First-patient-dosed in 1L Ph3 trial for GB491(CDK4/6)**
- **GB491 2L Ph3 trial on track**
- **First-patient-dosed in FIH trial for GB263T (EGFR/cMET/cMET) in AUS**

- **2 INDs approved by NMPA**
  - GB261(CD3/CD20) IND approval
  - GB263T (EGFR/c-Met/c-Met) IND approval
- **1 BLA approved by NMPAGB242 (Infliximab Biosimilar) NDA approval**
- **GB226 (PD-1) Priority Review for PTCL by NMPA**
- **GB2631 & GB263T EC Approval in CN**

Operation Efficiency

Clinical Development

IND / NDA / BLA Progerss



Discovery / Early Research

Business Development

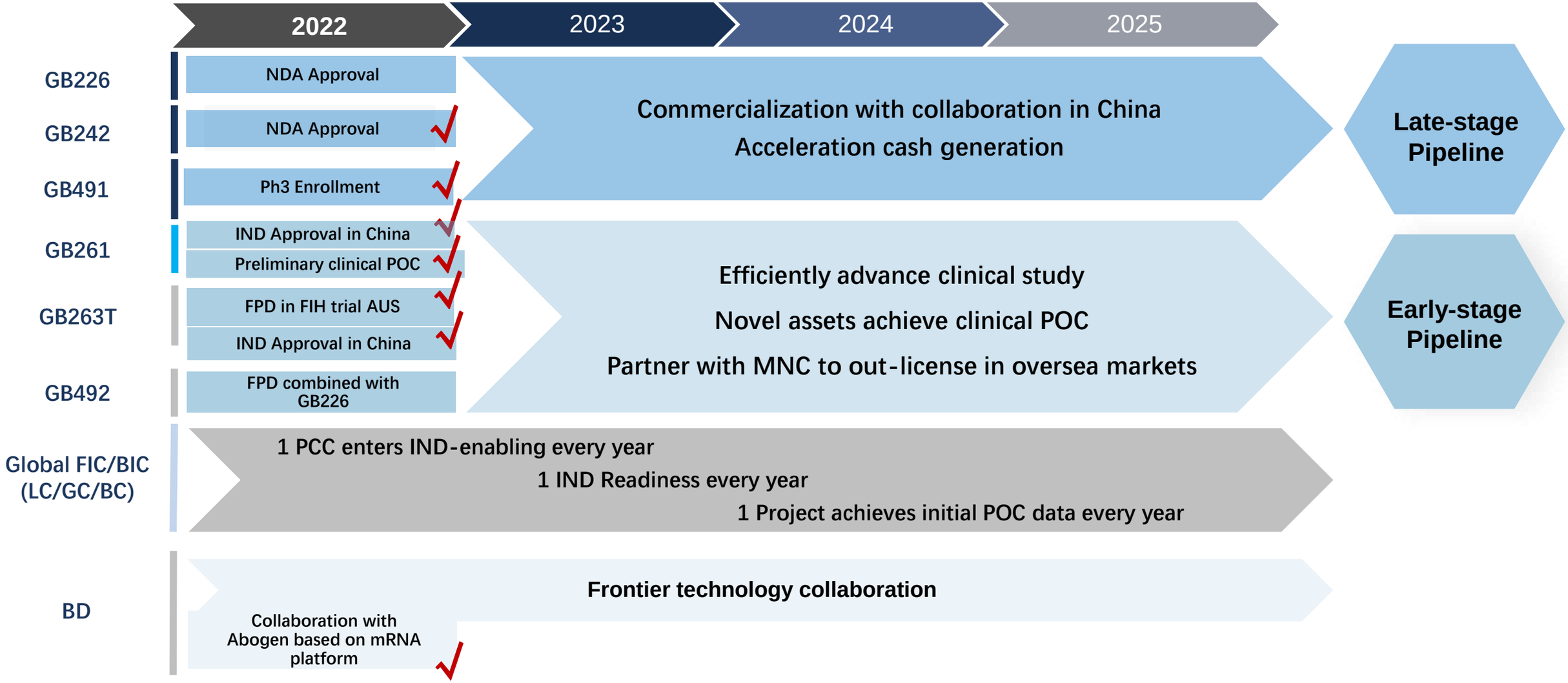
Respond to COVID

- **Established global innovative platform for IO Bs/MsAb FIC/BIC drug research and discovery**
  - Initiated 5 FIC/BIC bi/multi-specific antibodies projects
  - Nearly 10 innovative early research projects involving different molecular forms have been carried out, focusing on the field of tumor therapy.
  - 1 FIC/BIC potential drug candidate is expected to submit IND every year

- **Collaboration with Abogen in discovery and development of global innovative mRNA candidates**

- **Actively Resumed Work as COVID Controls Ease**
  - Listed in the second batch of enterprise to resume work
  - 26 colleagues returned to work during the epidemic
  - Early research and clinical work were accelerated
  - Completed more than 200 patients enrollment from March to May when the city was lockdown.

Focus & Acceleration——Achieved several goals of 2022 in advance
Maintain steady operation & development in next 3 years with current cash flow



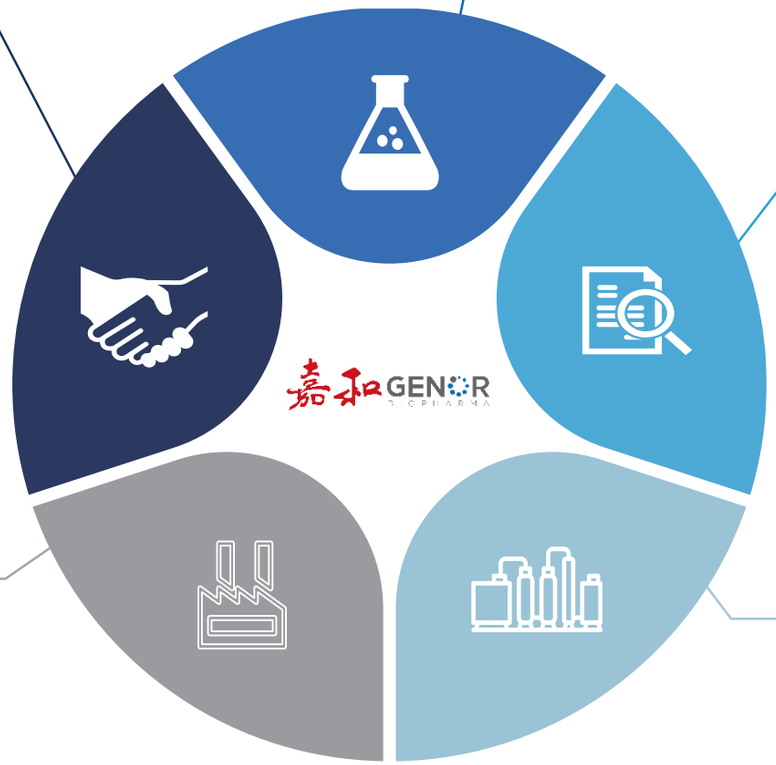
End-to-end Integrated Platform

Discovery

- IO bi/multi-specific antibody
- FIC/BIC potential drug design platform
- Immune check point inhibitor
- T-Cell Engager for solid tumors
- Cytokines drug conjugates

Business Development

- A proven track record of collaborating with biopharmaceutical and biotechnology companies globally
- Potential license-out and co-development projects
- mRNA collaboration
- Commercialization partners for GB242



Clinical and Regulatory

- Optimize clinical development strategy and plan to maximize compound value
- Internal and external cooperation
- Excellent execution, high quality and efficient clinical trial development program
- Communicate with drug regulatory authorities and drug review agencies to advance IND and NDA

Manufacturing

- Compliance with GMP operations and NMPA, FDA, and ICH guidelines
- Concentrated fed-batch (CFB) and continuous perfusion technologies
- Large bioreactors：3x200L，4x500L
- Higher cost efficiency
- Industry leading yield: 20g/L of PD-1

CMC

- Proven CMC capability
- Continuous-flow cell culture technology
- Bi/tri-specific antibody with higher titer and yield
- Titer: 5-6g/L

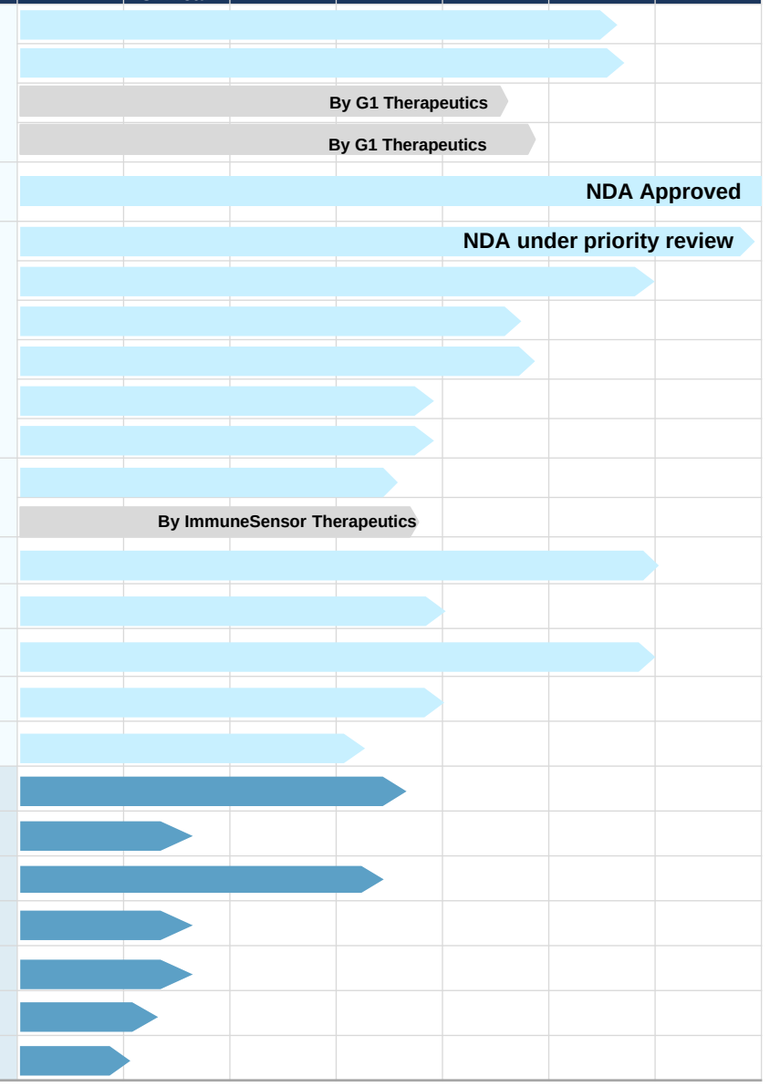
02

Pipeline Introduction

GENOR BIOPHARMA

A Robust Pipeline- Development Stage Assets Focusing on Global Opportunities

Product	Target/MoA (reference drug)	Indication	Classification	Commercial Rights
GB491	CDK4/6+AI (combo w/ letrozole)	1L HR+/HER2- BC	Novel (In-license)	APAC ex-JP(1)
	CDK4/6+SERD (combo w/ fulvestrant)	2L HR+/HER2- BC		
	CDK4/6+ EGFR (combo w/ osimertinib)	EGFR-Mutant NSCLC		
GB242	TNF-α (infliximab)	RA, AS, Ps, CD, UC	Biosimilar (In-house)	Worldwid
GB226	PD-1	r/r PTCL	Novel (In-license)	China
		2L+ Cervical Cancer		
		ASPS		
		r/r PMBCL		
	PD-1+VEGFR (combo w/ fruquintinib)	2L/3L+ EGFR+ NSCLC		
		2L+ mCRC		
GB492	PD-1 (combo w/ GB226*^)+STING	Solid Tumours	Novel (In-license)	APAC ex-JP(2)
GB221	HER2	HER2+ 1L/2L+ mBC	Novel (In-house)	Worldwide
GB223	RANKL	GCTB, PMO	Novel (Co-develop)	Worldwide
GB241	CD20 (rituximab)	1L DLBCL	Biosimilar (In-house)	Co-development
GB224	IL-6	Inflammatory Disease	Novel (In-license)	China
GB251	HER2 ADC	HER2+ 1L/2L+ mBC	Novel (Co-develop)	Worldwide
GB261	CD20×CD3	NHL	Novel (In-house)	Worldwide
GB262	PD-L1×CD55	Cancers	Novel (In-house)	Worldwide
GB263T	EGFR×c-Met×c-Met	NSCLC	Novel (In-house)	Worldwide
GB264	Claudin 18.2×CD3	GI Cancers	Novel (In-house)	Worldwide
GB266	PD-L1xLAG3xLAG3	Cancers	Novel (In-house)	Worldwide
GB267	Undisclosed	Cancers	Novel (In-house)	Worldwide
***	Undisclosed	Cancers	Novel (In-house)	Worldwide



*Notes: (1) Clinical trials are sponsored by G1 Therapeutics. (2) Clinical trial is sponsored by ImmuneSensor Therapeutics; * **four undisclosed candidates in discovery stage***

GB491 (Lerociclib) – Potential Best-in-Class CDK4/6 Inhibitor

Excellent Efficacy Profile & Better Tolerability

- Lerociclib is a potent, selective, CDK4/6 inhibitor with superior tolerability by improving its targeting and pharmacokinetic properties
- GB491 can be administrated continuously as good tolerability, thus it may maintain the drug exposure to continuously suppress the target
- Wider range of patients including pre-menopause and post-menopause.
- Phase 2 clinical data showed potential best in class efficacy and safety profile in the CDK4/6 class

Excellent Efficacy

	Lerociclib[1] Phase 1/2a (In progress)	Pfizer[2] Paloma-3	Hengrui[3] Dawna-1
Line setting	median 2L+	2L+	2L+
Treatment	Lerociclib + fulvestrant	Palbociclib+ fulvestrant	Dalpiciclib+ fulvestrant
mFU	(60.0% censored at last follow up)	8.5 mo	10.7 mo
mPFS	**28.6 mo**	**9.5 vs. 4.6 mo** (HR 0·46, 95% CI 0·36–0·59, P<0·0001).	**15.7 vs. 7.2 mo** （HR 0.42, 95% CI 0.31–0.58, P<0.0001).
ORR	31.6% [12.6, 56.6]	19% (15·0–23·6)	27% （21.5–33.0）

Previous Lines of Therapy	Lerociclib[1]	Pfizer[2] Paloma-3	Dalpiciclib[3] Dawna-1*
0	35%	24.2%	
1	25%	38%	72.6%
2	20%	25.9%	27.4%
≥3	20%	11.8%	

- The patients in GB491 2L+ phase 2 and Paloma-3 study experienced more previous lines of treatment

1.G1 Therapeutics, FDA, ESMO 2020 poster; data cutoff: 17 Apr 2020 Note [1]: for 150mg 每日两次给药组
2. Massimo Cristofanilli et al,Lancet Oncol 2016; 17: 425–39
3. Binghe Xu et al, https://doi.org/10.1038/s41591-021-01562-9
Note reported with* Previous Lines of EndocrineTherapy

GB491 (Lerociclib) – Potential best safety profile across the CDK4/6 drug class

- GB491 can be administrated continuously as it has less blood adverse reaction.
- GB491 has less gastrointestinal adverse reactions in all grades and has no gastrointestinal adverse reactions in grade 3 or above.

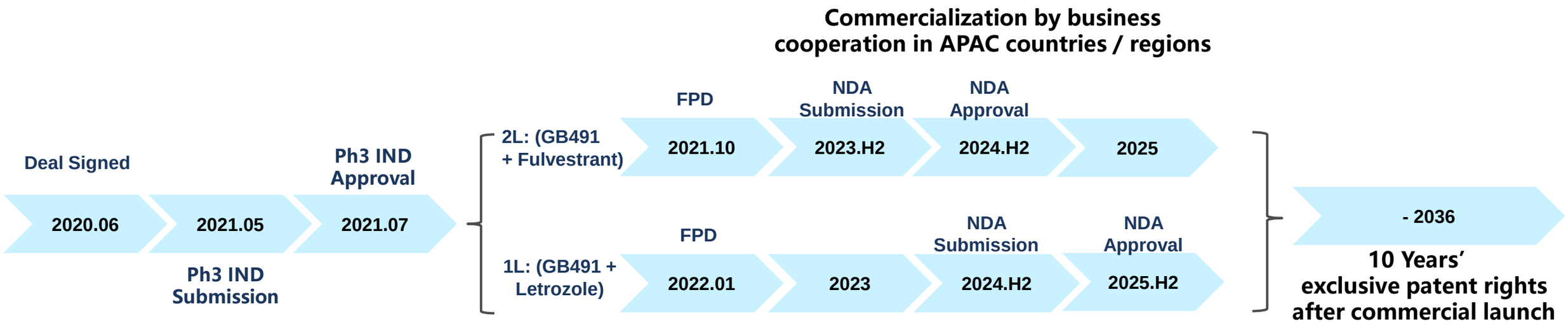
Longer treatment duration requires therapeutics with better tolerability

Potentially best safety profile across the CDK4/6 drug class

	Lerociclib [1]		Abemaciclib		Palbociclib		Ribociclib	
Trial	**NCT02983071**		**MONARCH-2**		**PALOMA-3**		**MONALEESA-3**	
Phase	I/IIa		III		III		III	
Line setting	Median 2L+		1/2L		1L+ (2L 40%, 3L 25%)		1/2L	
Treatment	Lerociclib + fulvestrant		Abemaciclib + fulvestrant		Palbociclib + fulvestrant		Ribociclib + fulvestrant	
AE (%)	**All**	**Gr3/4**	**All**	**Gr3/4**	**All**	**Gr3/4**	**All**	**Gr3/4**
Neutropenia	55%	**35%**	46%	**27%**	79%	**62%**	70%	**53%**
Leukopenia	40%	**15%**	28%	**9%**	46%	**25%**	28%	**14%**
Nausea	15%	**0%**	45%	**3%**	29%	0%	45%	1%
Diarrhea	25%	**0%**	86%	**13%**	19%	0%	29%	1%

Source: G1 Therapeutics, FDA, ESMO 2020 poster; data cutoff: 17 Apr 2020 Note [1]: for 150mg Bid

GB491 (Lerociclib) – Expects to submit NDA in China in H2 2023

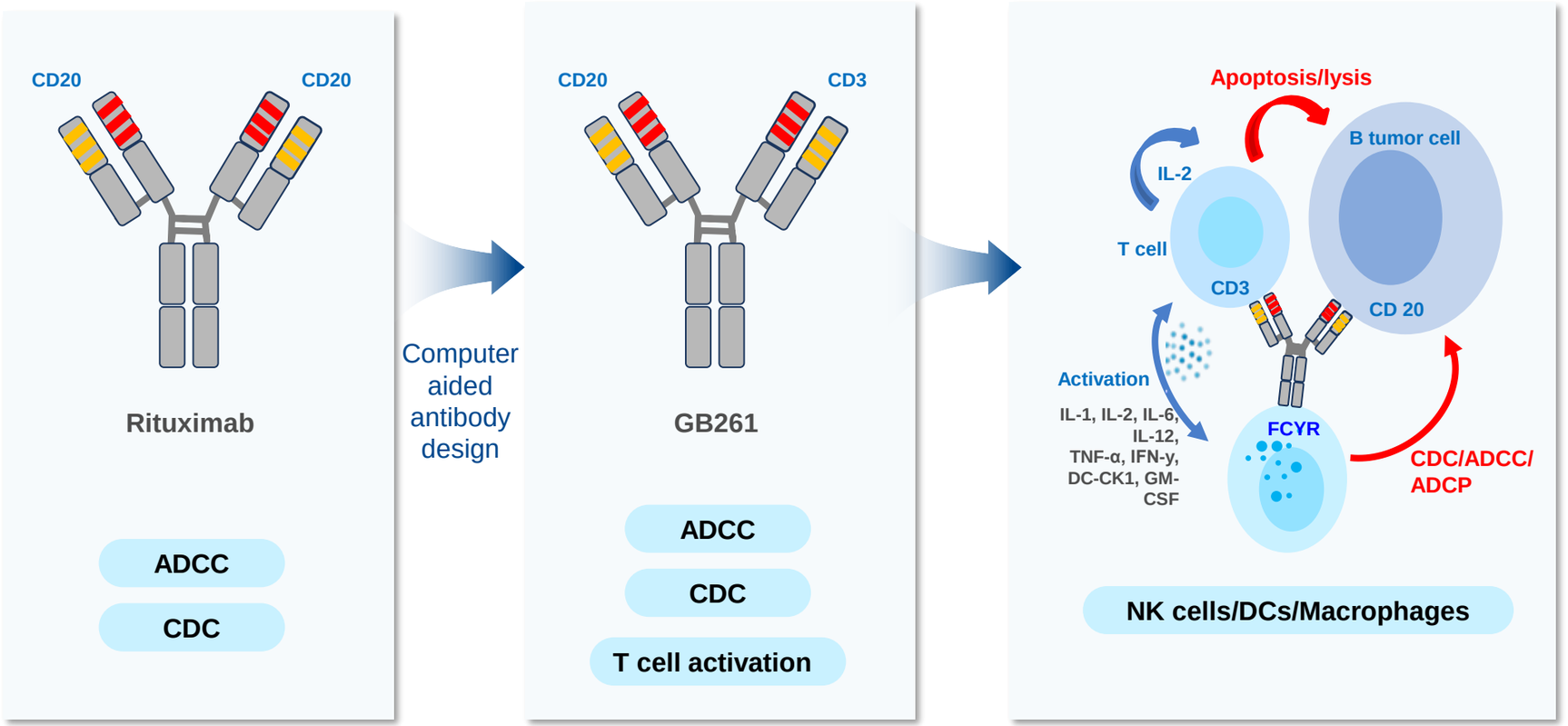


GB261 – A Highly Differentiated CD20/CD3 BsAb for B-cell Lymphoma

CN IND approval in May 2022
Phase 1 clinical trial kicked off in China in August 2022

The first T-cell engager with super low CD3 binding affinity and maintaining Fc effector functions (ADCC and CDC) , rendering better safety and multiple mechanisms to better kill cancer cells.

CDR grafting and backmutation

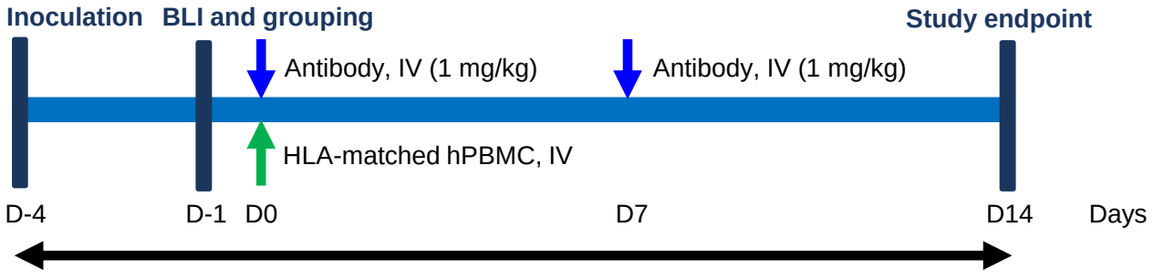


Compare with REGN1979 analog

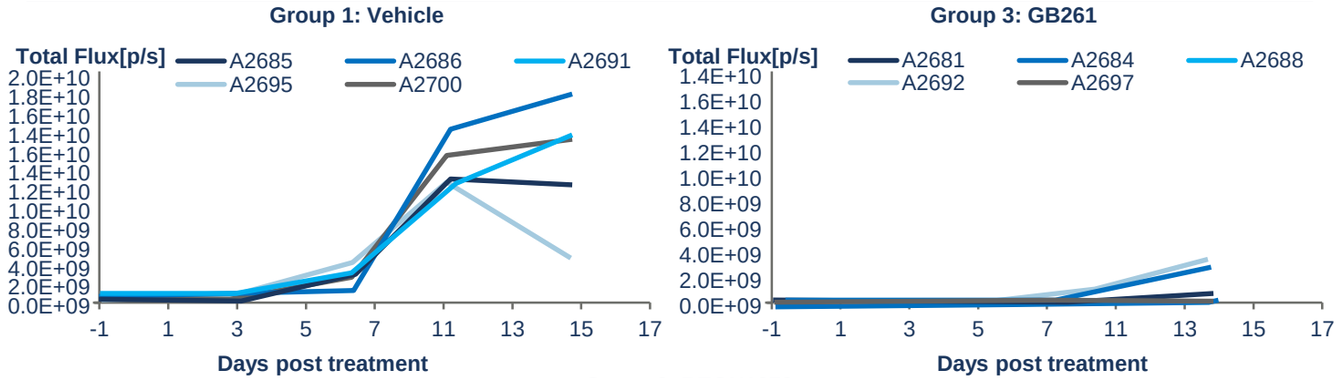
- **Induces more Rituxan-resistant Raji cell killing in PMBC-engrafted B-NDG mice**
- **stimulates less cytokine release**

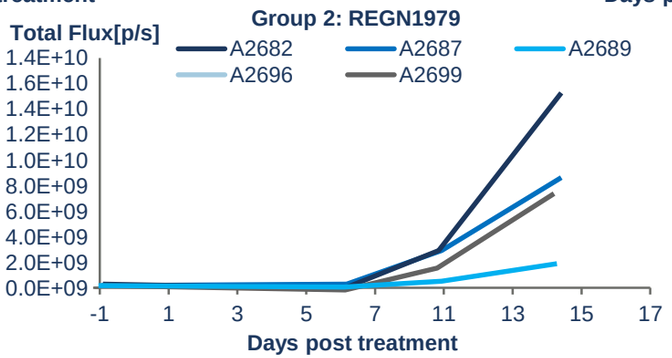
GB261 Significantly Inhibits Rituximab-resistant Tumor Growth (in vivo)

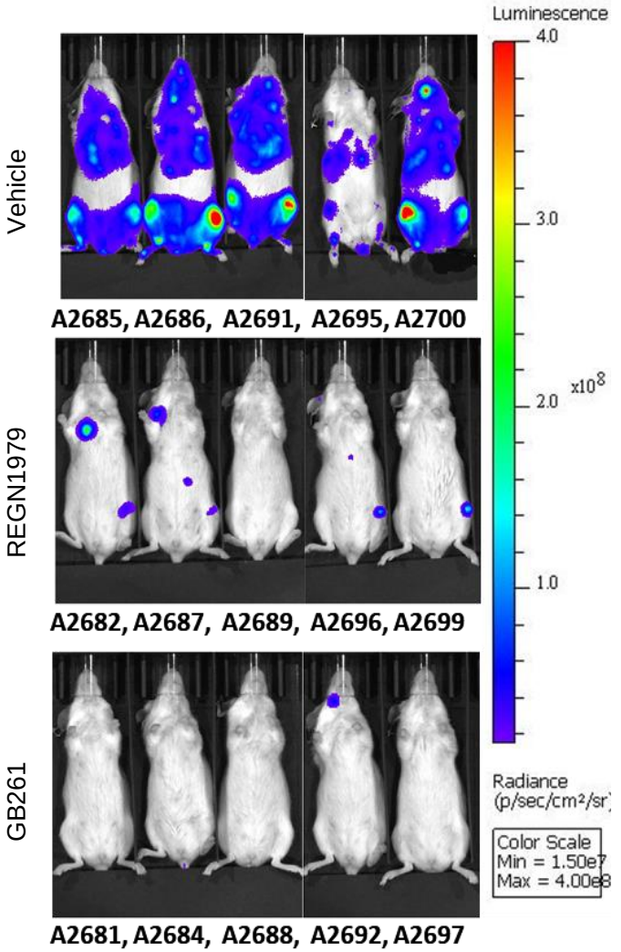
GB261 induces more Rituxan-resistant Raji cell killing in PMBC-engrafted B-NDG mice than REGN1979 analog.



Monitor tumor load (BLI) and bodyweight every three days

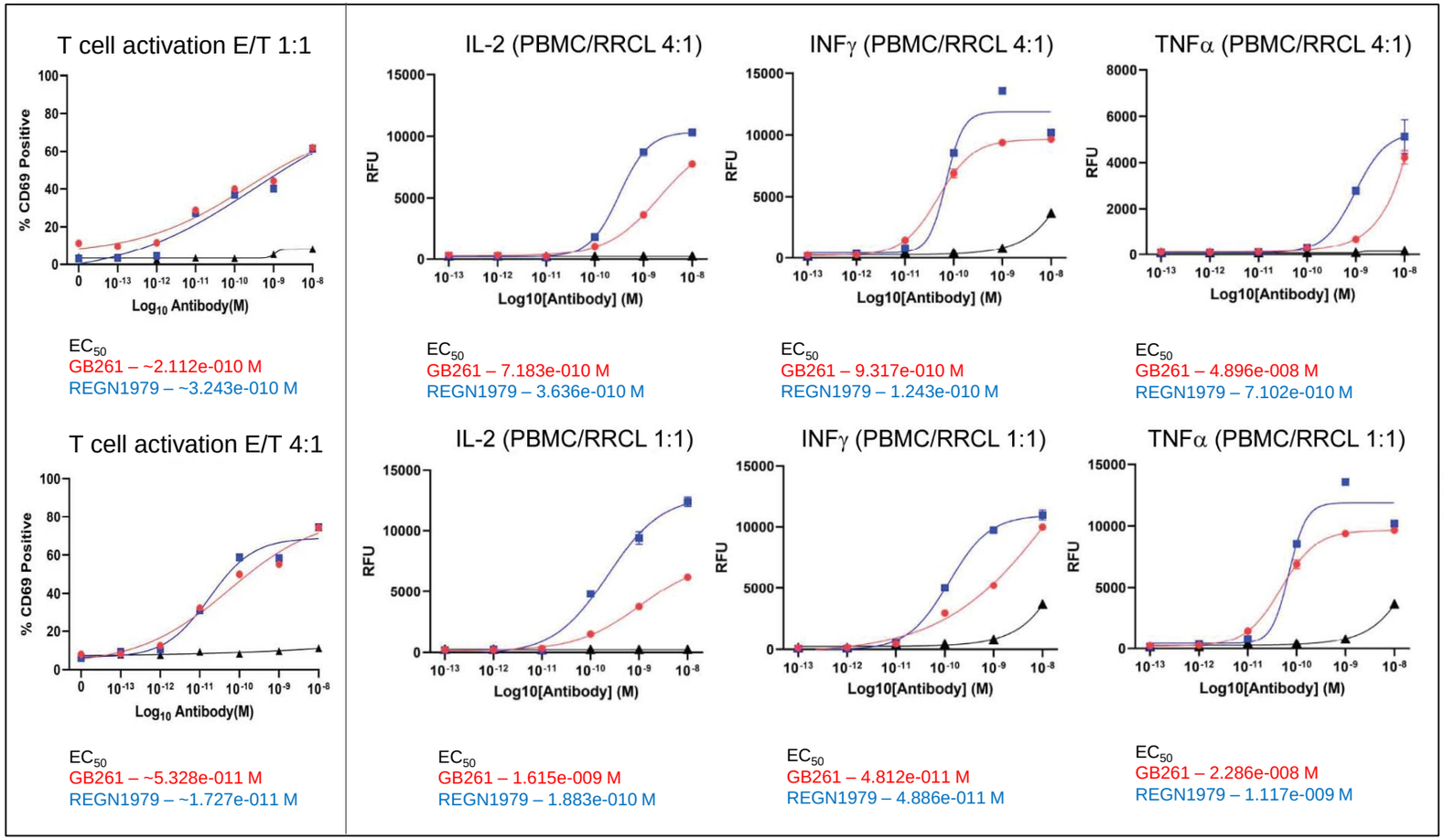






GB261 Induces T cell Activation with Less Cytokine Releases

GB261 stimulates less cytokine release compared to that of REGN1979 analog.



GB261 - The preliminary clinical POC achieved for GB261

Clinical and Regulatory Progress in 1H2022:

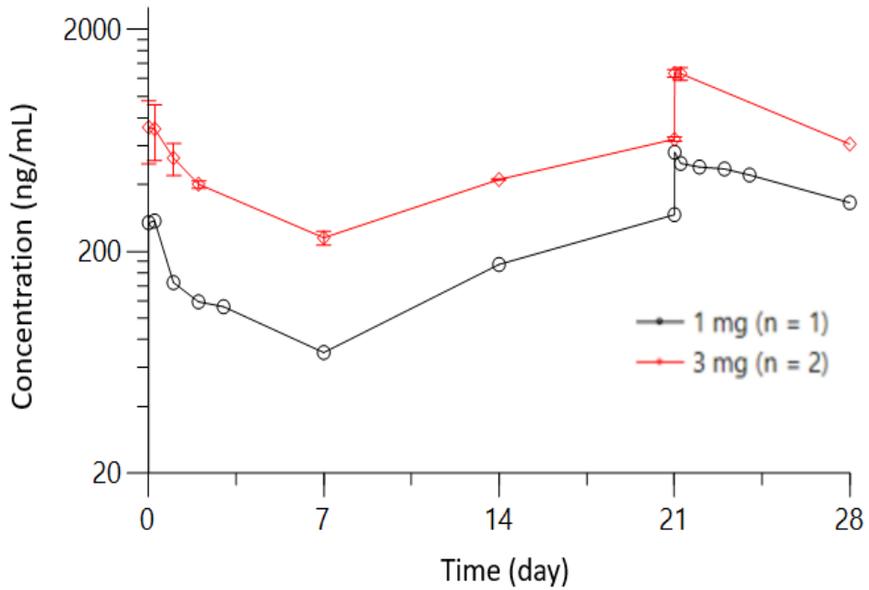
- **Australia:**
  - 1mg & 3mg completed
  - 10mg ongoing
  - **Preliminary POC achieved**
  - **Objective response observed**
- **China:**
  - **Phase 1 clinical trial kicked off**
  - FPI achieved

GB261 Clinical Data Conforms to MOA and Pre-clinical Discovery

Preliminarily showed higher starting dose

Drug Candidate	GB261	Mosunetuzumab (RG7828)	Odronextamab (REGN1979)	Glofitamab (RG6026)
Starting Dose	1mg	50μg	30 μg	5 μg

Complete 1mg and 3mg dose groups
Preliminary POC, PK and cytokine data conform to MOA and pre-clinical discovery



Intravenous administration of 1mg and 3mg shows a linear PK; Drug trough concentration reaches steady state after 4 weeks of dosing

- The terminal half-life of GB261 is estimated to be around 1 week

No cytokine release in 1mg group while little cytokine release in 3mg group

Clinical efficacy is proved in 3mg group

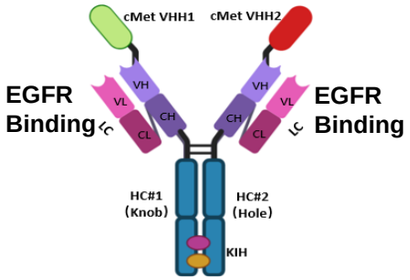
10mg group trial is under way

GB263T – the First EGFR/cMET/cMET Tri-specific for NSCLC

Global rights, global innovation, blockbuster potential

In comparison with JNJ-61186372，GB263T is differentiated in design

GB263T



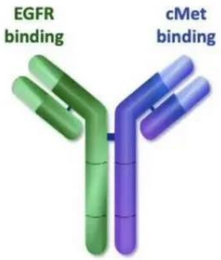
Multiple MOAs

- Inhibit EGFR/c-MET relevant signaling
- Mediate receptor endocytosis
- ADCC

- 2 : 2，asymmetric structure
- Binding to two “c-Met” with different epitopes
- IgG1，ADCC enhanced through AAs mutation

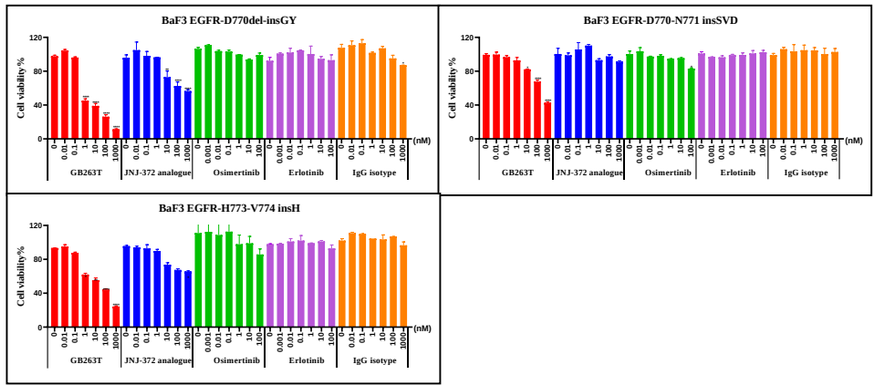
VS

JNJ-61186372 (Amivantamab)



- 1 : 1, asymmetric structure
- Binding to one “c-Met”
- IgG1，ADCC enhanced through high afucosylation

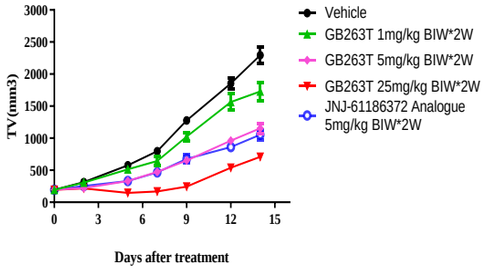
GB263T inhibits activity of cells with EGFR ex20ins mutations



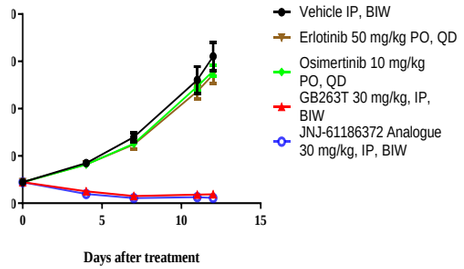
GB263T showed a dose-dependent inhibition of the viability of cells containing 3 different EGFR exon 20 insertion mutations（including D770del-insGY，D770-N771 insSVD, and H773-V774 insH）

GB263T induces tumor killing in EGFR mutations CDX models

EGFR Ex20ins (D770Del/InsGY)



EGFR Ex19del/T790M/C797S



GB263T inhibits tumor growth in EGFR ex20ins models with three different mutations: EGFR D770Del/InsGY, EGFR D770_D770_N771insSVD, and EGFR Ex19del/T790M/C797S

GB263T – Trials in AUS and China

Cross-Department Cooperation

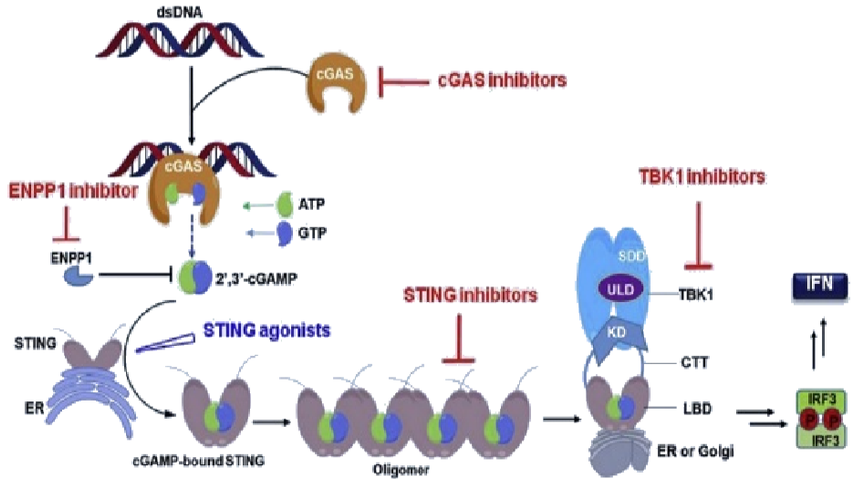
- **Cooperated with world famous PI** to design clinical trial
- Finalized the clinical trial scheme within one day while the Tox data readout
- From CMC initiation to FIH submission in Australia **within 12 months**. Better than industry average
- **Expression level of 5-6g/L and purity of 99.5%**
- **140 mg dose cohort completed, dose escalation ongoing**

Clinical Development Plan

GB492 – A Potentially First-in-class STING Agonist in China

Complete 400μg mono clinical trial, start combo escalation with PD-1

Mechanism of Action



- STING is the major mediator of innate immune sensing of cancerous cells
- STING agonists can activate the cGAS-STING signaling and significantly enhance the efficacy of cancer immunity cycle when using in combo with other immune checkpoint inhibitors (ICI)
- Multiple studies show that STING agonist may be used as a new immune stimulatory therapy

STING agonist, as an immune stimulatory therapy, may further increase the response of immune checkpoint inhibitors for patients

Merck's trial demonstrated robust efficacy of PD-1 + STING combination therapy comparing to single agent

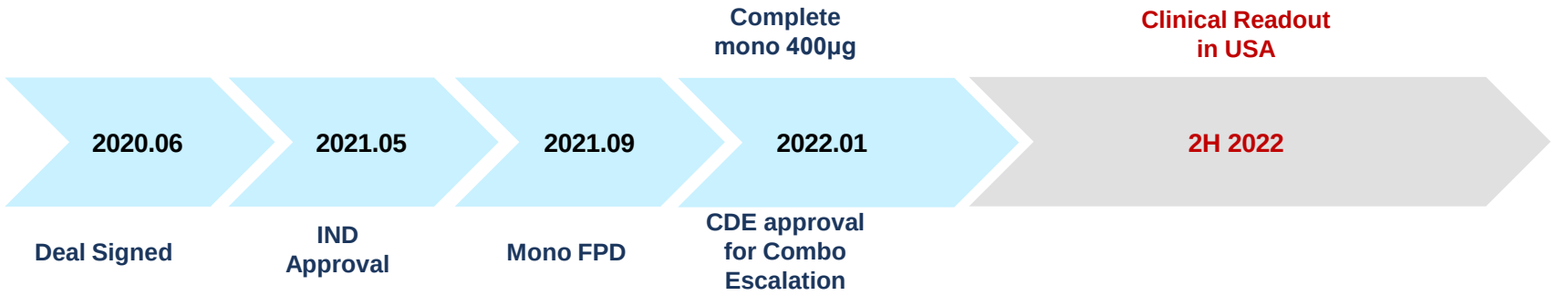
- Preliminary data from Merck's Phase 1 clinical trial for a STING agonist as monotherapy and in combination with Keytruda, in patients with advanced solid tumors or lymphomas
  - The **combination arm had partial responses of 43%** (three out of the seven patients) in HNSCC
  - By contrast, **Keytruda monotherapy showed ORR of 18%** in KEYNOTE 012 trial in platinum-refractory HNSCC

GB492 in combo with GB226 (PD-1) is potentially the first-in-class therapy in China

- ImmuneSensor Therapeutics, our licensor, is currently conducting a Phase 1/2 trial for STING alone or in combo with ICI in the US for solid tumors
- We **plan to develop GB492 in combination with GB226 as a first-in-class therapy** for solid tumors in China

Source: CIC, ESMO

GB492 – Advancing Clinical Development



Progress Achievements:

- **IND Approval** for an innovative FIH trial Design combining 2 dose escalation in one study
  - GB492 mono
  - GB492 + PD-1 combo
- GB492 Mono Initial clinical data: 400 μg Chinese pts safety well tolerated, comparable to US safety data
- **Waive Mono Escalation** in China and directly start GB492 + GB226 (PD-1) combo escalation , thus advance 3-6 months than regular method

Clinical Development Strategy

To leverage US POC data

GB492 + PD-1

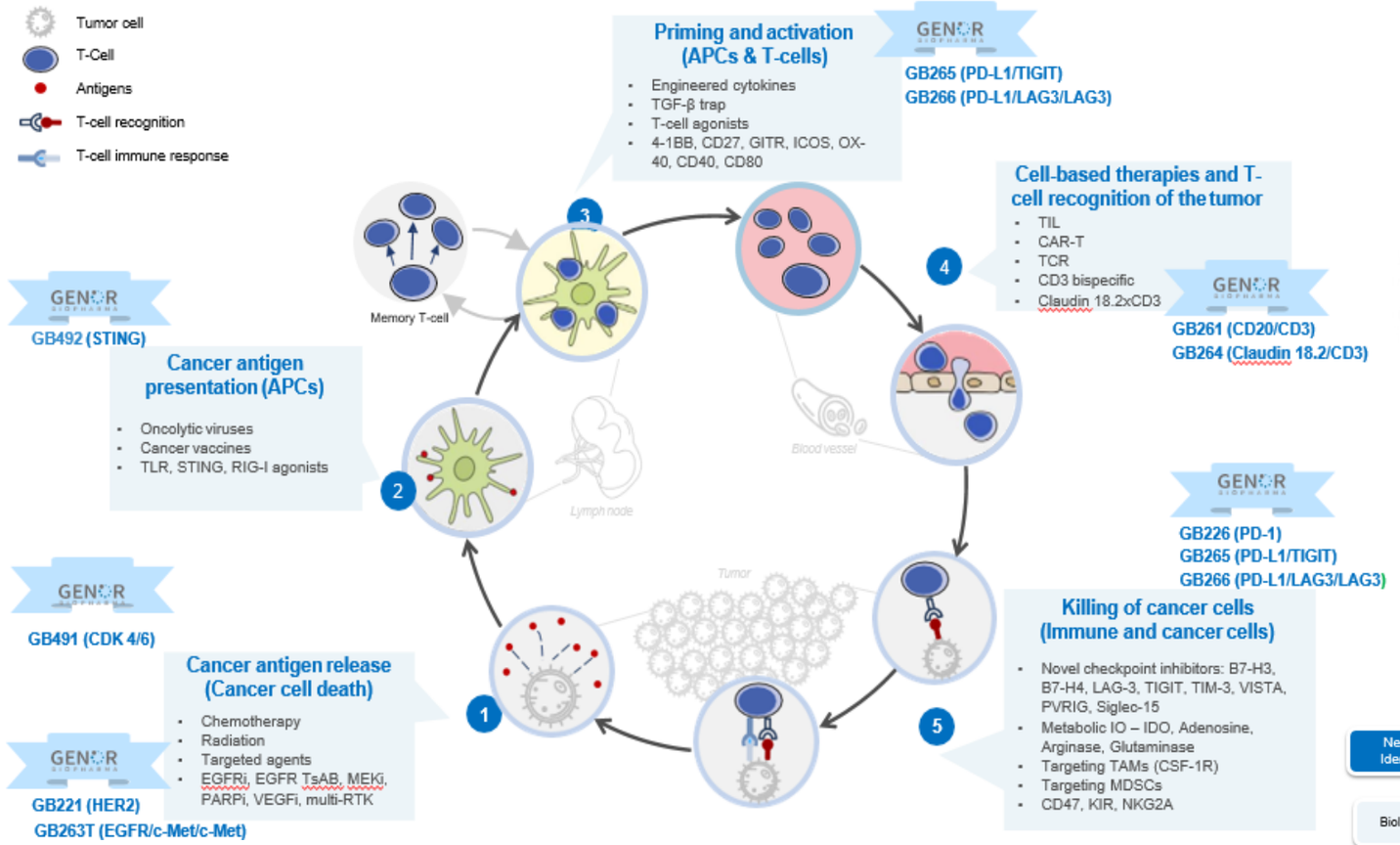
Pivotal Studies in multiple tumor types

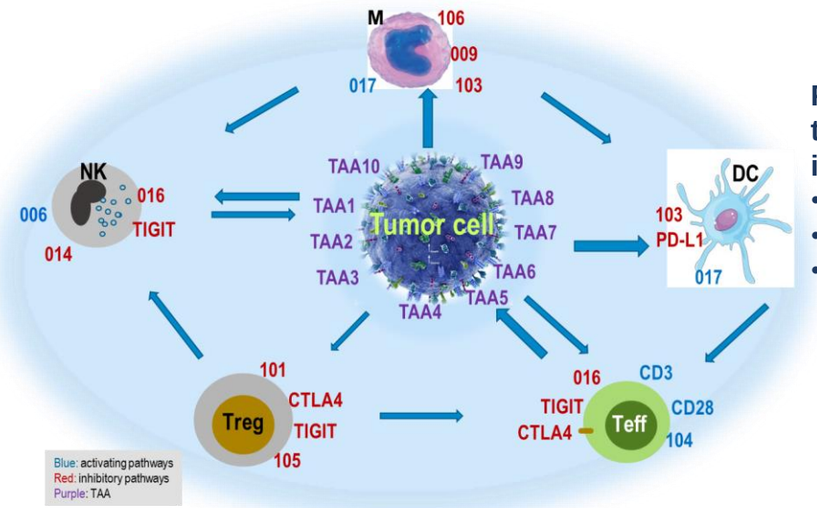
- HNSCC
- HCC
- TNBC
- Other Solid Tumors

Source: CIC, ESMO

FIC Drug Design Strategy and Integrated Drug Development Platform

FIC Drug Design Strategy





Focusing on tumor immunology

- BsAb/TsAb
- TCEs
- Cytokines conjugates

FIC Drug Design Platform

New Target Identification	Antibody Discovery	Modalities	Lead Screen & Characterization	Translational Medicine	Preclinical PK / PD / Tox	Information/ intelligence
Biology driven	mAb development	Immune check point inhibition BsAb/MsAb	Binding / blocking Specificity / epitope	*In vitro / ex vivo* analysis of human samples	PK / PD	
Unmet medical needs	BsAb / tri-specific Ab development	T-Cell Engager for solid tumors	Cross-species reactivity	Biomarker analysis (cellular, protein, gene levels)	Pre-tox GLP-tox	
Optimal format	VHH (Alpaca) phage display Yeast display	Cytokines drug conjugates	Biochemical assays Cellular assays			
Innovative molecular design		mRNA	*In vivo* models			

New Discovery-stage Pipeline :
Focusing on IO FIC Antibodies While Exploring Cutting-edge Technology, one IND per year

Discovery-stage pipeline

pipeline		Indications	Lead discovery
Bi/multi-specific antibody / fusion protein	GBD201	NSCLC, ESCC,other solid tumors	
	GBD202	NSCLC, GC, other solid tumors	
	GBD209	NSCLC, pancreatic cancer, other solid tumors	
	GBD211	NSCLC, HCC, other solid tumors	
	GBD212	NSCLC, HNSCC, other solid tumors	
	GBD208	NSCLC, pancreatic cancer, other solid tumors	
	GBD204	SCLC and other solid tumors	
mRNA	GBD401	Solid tumors	

FIC

- Comprehensive assessment before entering into next stage.
- Advance only FIC/BIC potential candidates

IO Focus

- Immune Check Point BsAb/TsAb
- T-Cell Engager for solid tumour
- Cytokines Drug Conjugates

IND

- E: 1 IND per year

Upcoming Events

Upcoming Milestones

Key Events	Timing
Expected milestones achieved in advance	
GB242 (TNF-α) – Commercial Approval	Feb 2022
GB261 (CD20/CD3) – IND Approval in China	May 2022
GB261 (CD20/CD3) – Initial POC readout	July 2022
GB263T (EGFR/cMet/cMet) – EC approval	March 2022
GB263T (EGFR/cMet/cMet) – FPD in Australia	May 2022
GB263T (EGFR/cMet/cMet) – IND Approval in China	June 2022
Achieve mRNA anti-cancer drug discovery collaboration	May 2022
Upcoming milestones of Core Projects	
GB242 (TNF-α) – Commercial Launch	2H2022
GB226 (PD-1) – NDA approval for 2L r/r PTCL	2022
GB491 (CDK4/6) – Last patient first dose 1L Ph3	2023
GB491 (CDK4/6) – NDA submission for 1L/2L HR+/HER2- mBC	2L: 2023 H2 / 1L: 2024 H2
GB263T (EGFR/cMet/cMet) – Initial POC readout	2023
Expected milestones of early-discovery-stage pipelines	
1 IND for FIC/BIC potential candidate every year	

04

Financial Overview

Financial Overview – Income Statement

RMB' mn	Six Months Ended 30 June 2022	2021
Revenue	3.0	-
Cost of revenue	0.8	-
Gross Profit	**2.2**	**-**
Selling expenses	(63.0)	(27.1)
Administration expenses	(84.1)	(117.4)
Research and Development expenses	(295.1)	(271.5)
Other income	4.6	5.6
Other (losses)/gains-net	(0.1)	16.2
Operating loss	**(435.5)**	**(394.2)**
Finance Income	27.9	7.4
Finance Costs	(1.7)	(19.7)
Finance income/(costs)-net	26.2	(12.3)
Loss before income tax	(409.3)	(406.5)
Income tax credit	2.7	4.0
Loss for the six months ended 30 June	**(406.6)**	**(402.5)**

** All numbers are rounded to one decimal place*

Revenue

- Revenue was generated by providing research and manufacturing services to customers under fee-for-service contracts.

Expenses

- R&D expenses increased, mainly due to the increase in new drugs development fee and ongoing clinical trials expenses.
- The decrease in administration expenses was primarily due to the decrease of employee benefit expenses for managerial and administrative personnel.
- The increase in selling expenses was due to the increase in employee benefits expenses of commercial personnel.

Net loss for the six months ended 30 June 2022

- Net loss for the six months ended 30 June 2022 was RMB 406.6mn

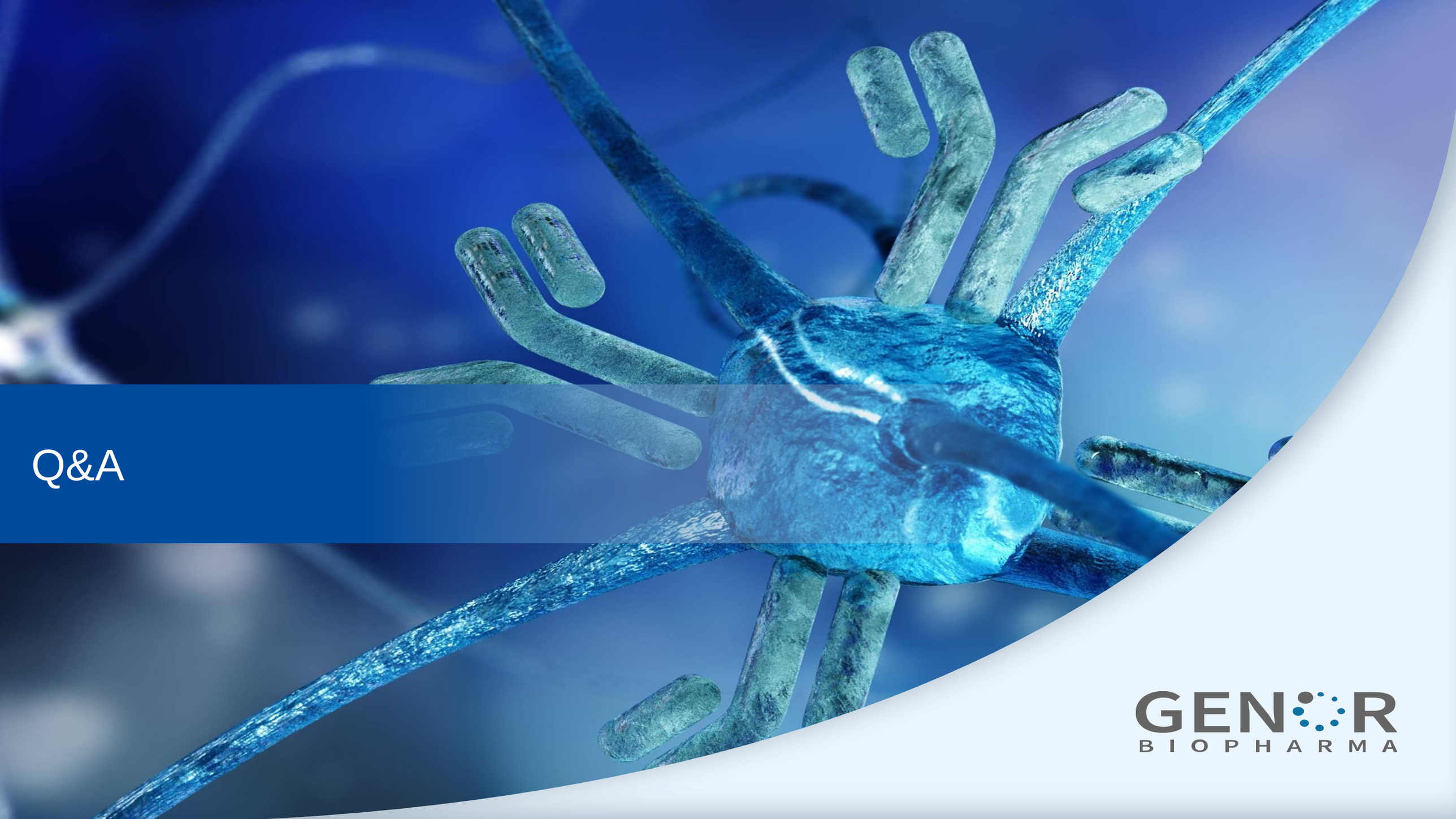
Financial Overview – Balance Sheet

RMB' mn	Jun-22	Dec-21
Cash and cash equivalents	1,858.2	2,200.6
Restricted bank deposits	-	2.0
Inventories	46.5	49.7
Contract cost	1.3	1.8
Other receivables, deposits and prepayments	91.0	132.5
Total Current Assets	**1,997.0**	**2,386.6**
Property, plant and equipment	192.2	200.0
Right-of-use assets	51.5	23.3
Intangible assets	166.5	171.1
Other receivables, deposits and prepayments	12.6	76.1
Deferred income tax assets	7.9	5.7
Total Non-Current Assets	**430.7**	**476.2**
Total Assets	**2,427.7**	**2,862.8**
Trade payables	92.7	129.7
Contract liabilities	4.9	5.6
Other payables and accruals	115.6	124.9
Short-term borrowings	-	29.7
Lease liabilities	14.8	7.6
Amounts due to related parties	2.4	4.1
Provision	-	7.9
Deferred income	3.7	3.7
Total Current Liabilities	**234.1**	**313.2**
Lease liabilities	40.0	20.1
Amounts due to related parties	3.4	5.0
Deferred income	15.8	18.1
Deferred income tax liabilities	12.9	13.3
Total Non-Current Liabilities	**72.1**	**56.5**
Total Liabilities	**306.2**	**369.7**
Total Equities	**2,121.5**	**2,493.1**

Cash Balance

- As at 30 June, 2022, our total cash and cash equivalents were RMB 1,858.2m.

** All numbers are rounded to one decimal place*



Q&A

GENOR BIOPHARMA

1H22 Interim Results Presentation

August 2022

嘉和 GENOR BIOPHARMA

股票代码:6998.HK