

1H22 Interim Results Presentation

August 2022



股票代码:6998.HK



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01

Business Review

嘉和 GENOR
BIOPHARMA

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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

Operation 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

Clinical Development



- **2 INDs approved by NMPA**
 - GB261(CD3/CD20) IND approval
 - GB263T (EGFR/c-Met/c-Met) IND approval
- **1 BLA approved by NMPA GB242 (Infliximab Biosimilar) NDA approval**
- **GB226 (PD-1) Priority Review for PTCL by NMPA**
- **GB2631 & GB263T EC Approval in CN**

IND / NDA / BLA Progress



Discovery / Early Research



- **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

Business Development

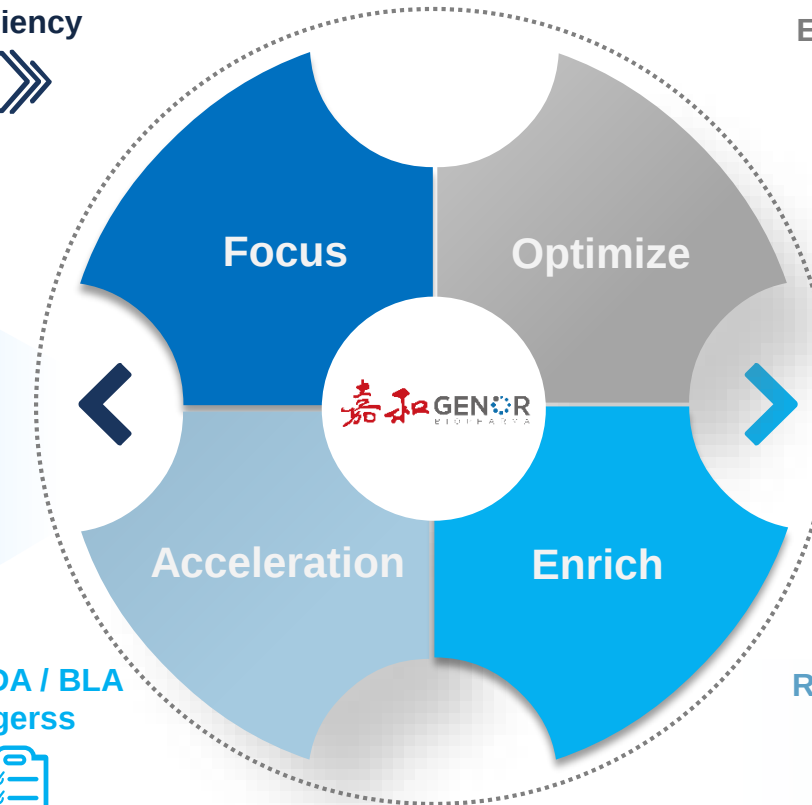


- **Collaboration with Abogen in discovery and development of global innovative mRNA candidates**

Respond to COVID

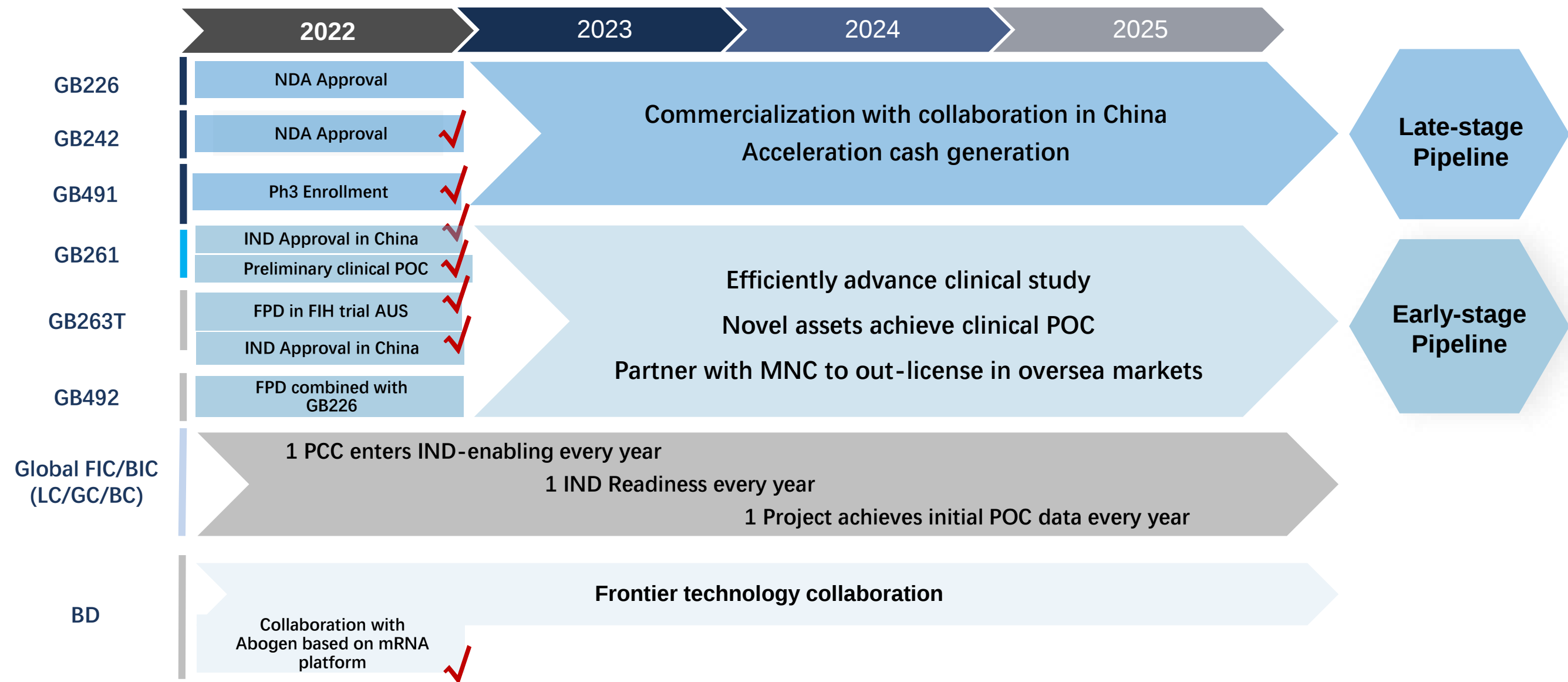


- **Actively Resumed Work as COVID Controls Ease**
 - Listed in the second batch of enterprise to resume work
 - 26 colleagues returned to work during the epidemic
 - Early research and clinical work were accelerated
 - Completed more than 200 patients enrollment from March to May when the city was lockdown.





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

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

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

Discovery

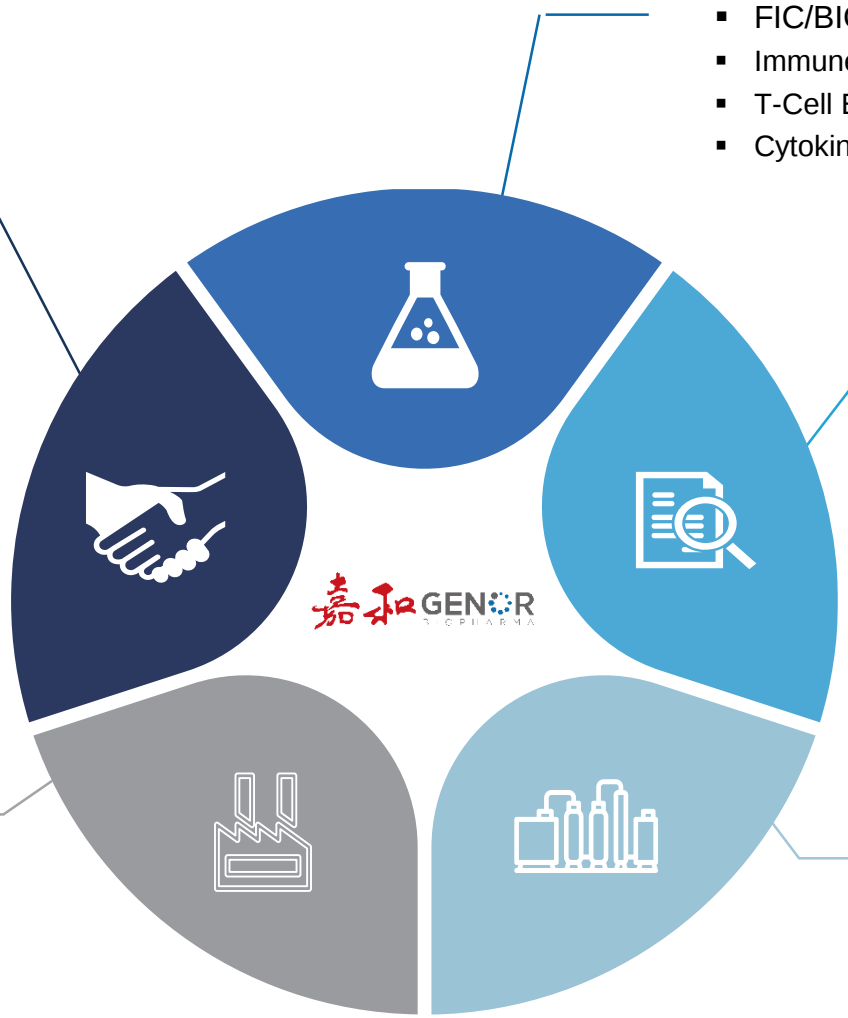
- IO bi/multi-specific antibody
- FIC/BIC potential drug design platform
- Immune check point inhibitor
- T-Cell Engager for solid tumors
- Cytokines drug conjugates

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

CMC

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



The background of the slide is a deep blue field filled with a complex network of glowing blue and yellow lines, resembling a neural network or a molecular structure. Two prominent, larger, textured blue spheres with multiple thin, radiating lines are positioned in the center and right. The overall aesthetic is high-tech and scientific.

02

Pipeline Introduction



A Robust Pipeline- Development Stage Assets Focusing on Global Opportunities

Product	Target/MoA (reference drug)	Indication	Classification	Commercial Rights	Discovery	Pre – Clinical	IND	Phase 1	Phase 2	Pivotal	NDA Review
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							NDA Approved
GB226	PD-1	r/r PTCL	Novel (In-license)	China							NDA under priority review
		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 $\times$ CD3	NHL	Novel (In-house)	Worldwide							
GB262	PD-L1 $\times$ CD55	Cancers	Novel (In-house)	Worldwide							
GB263T	EGFR $\times$ c-Met $\times$ c-Met	NSCLC	Novel (In-house)	Worldwide							
GB264	Claudin 18.2 $\times$ CD3	GI Cancers	Novel (In-house)	Worldwide							
GB266	PD-L1 $\times$ LAG3 $\times$ LAG3	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>

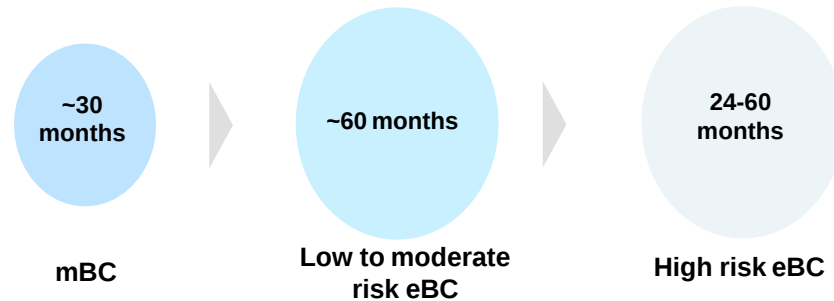
Note* reported with Previous Lines of Endocrine Therapy



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



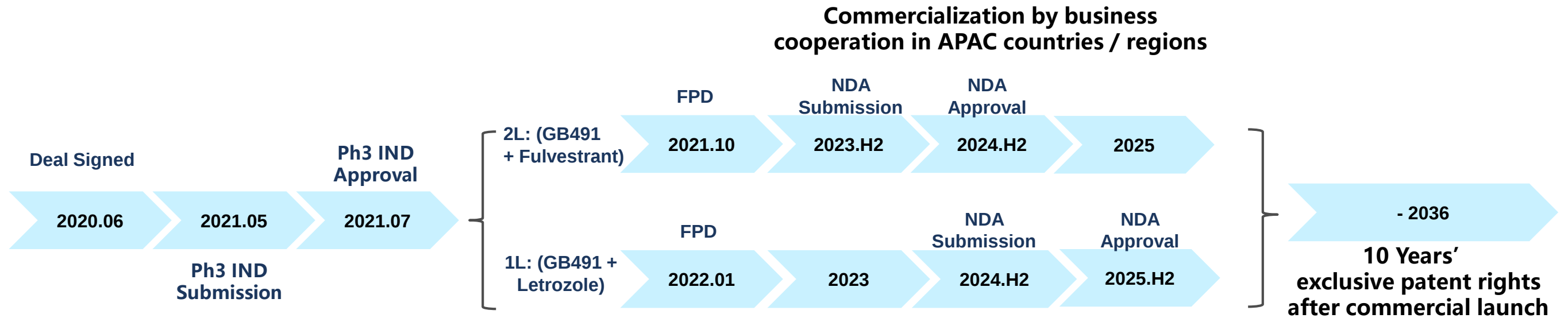
Potentially best safety profile across the CDK4/6 drug class

Trial	Lerociclib ¹		Abemaciclib		Palbociclib		Ribociclib	
	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

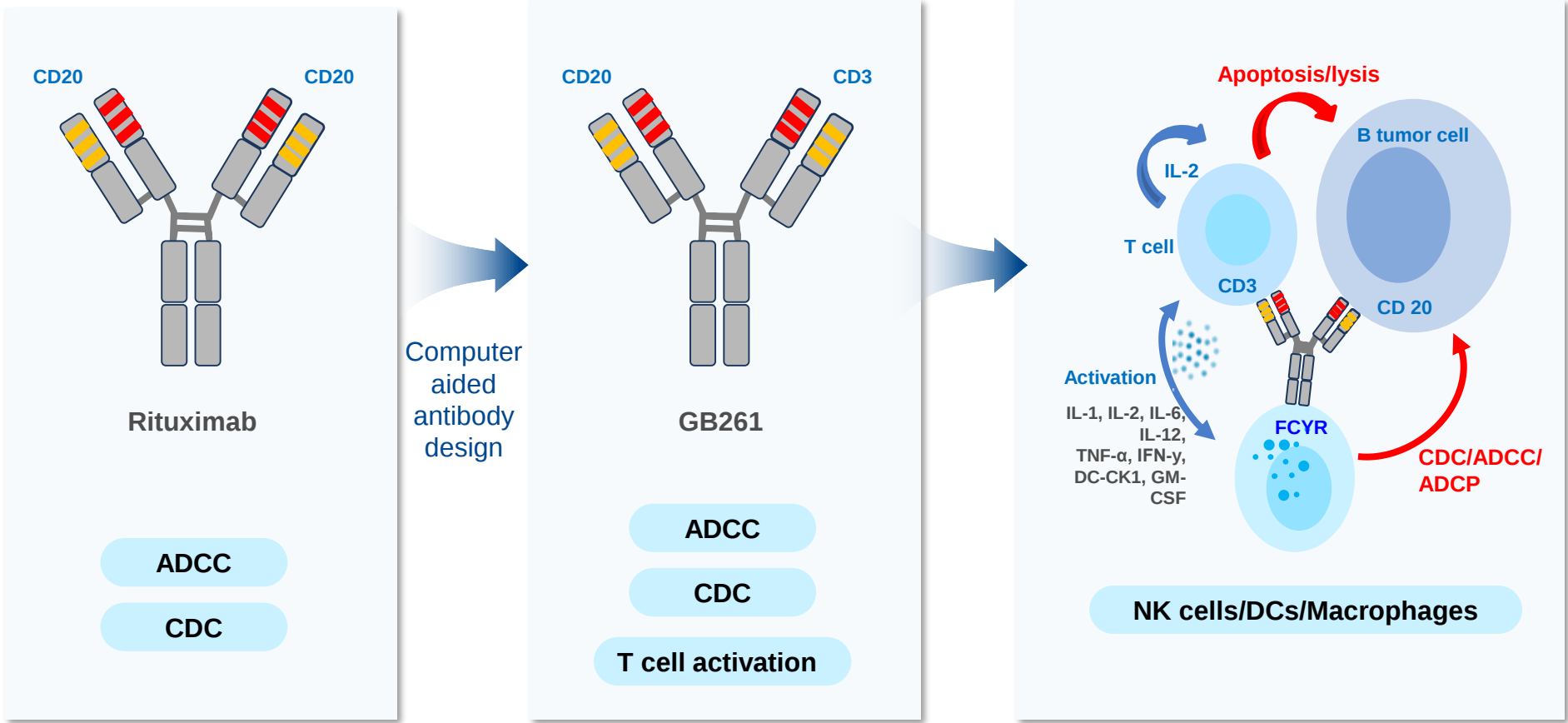
CN IND approval in May 2022

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

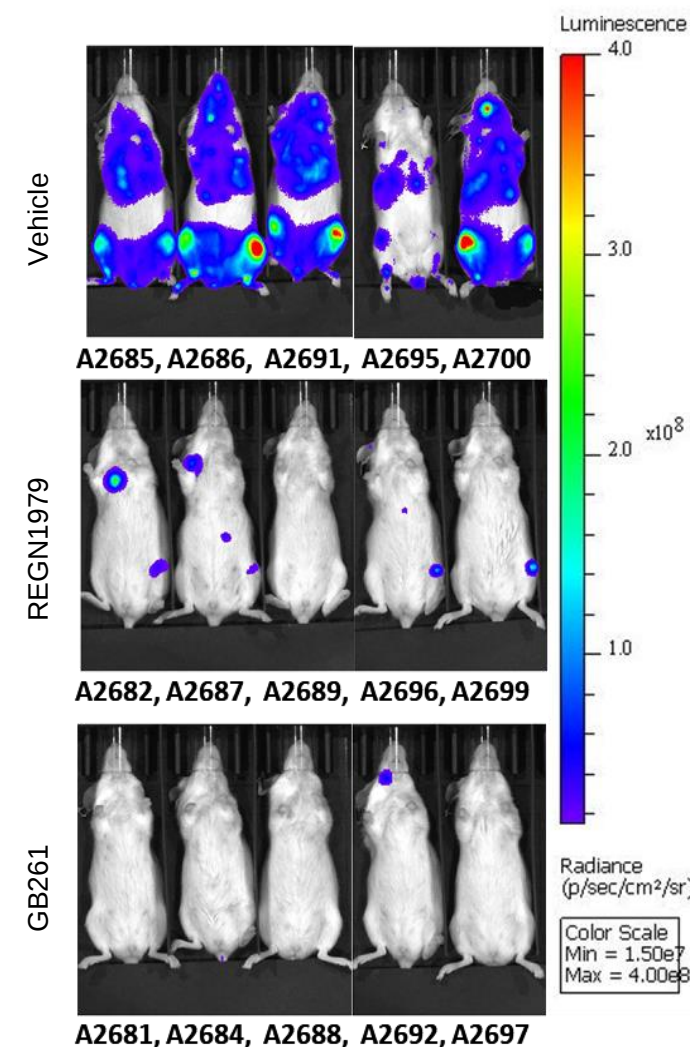
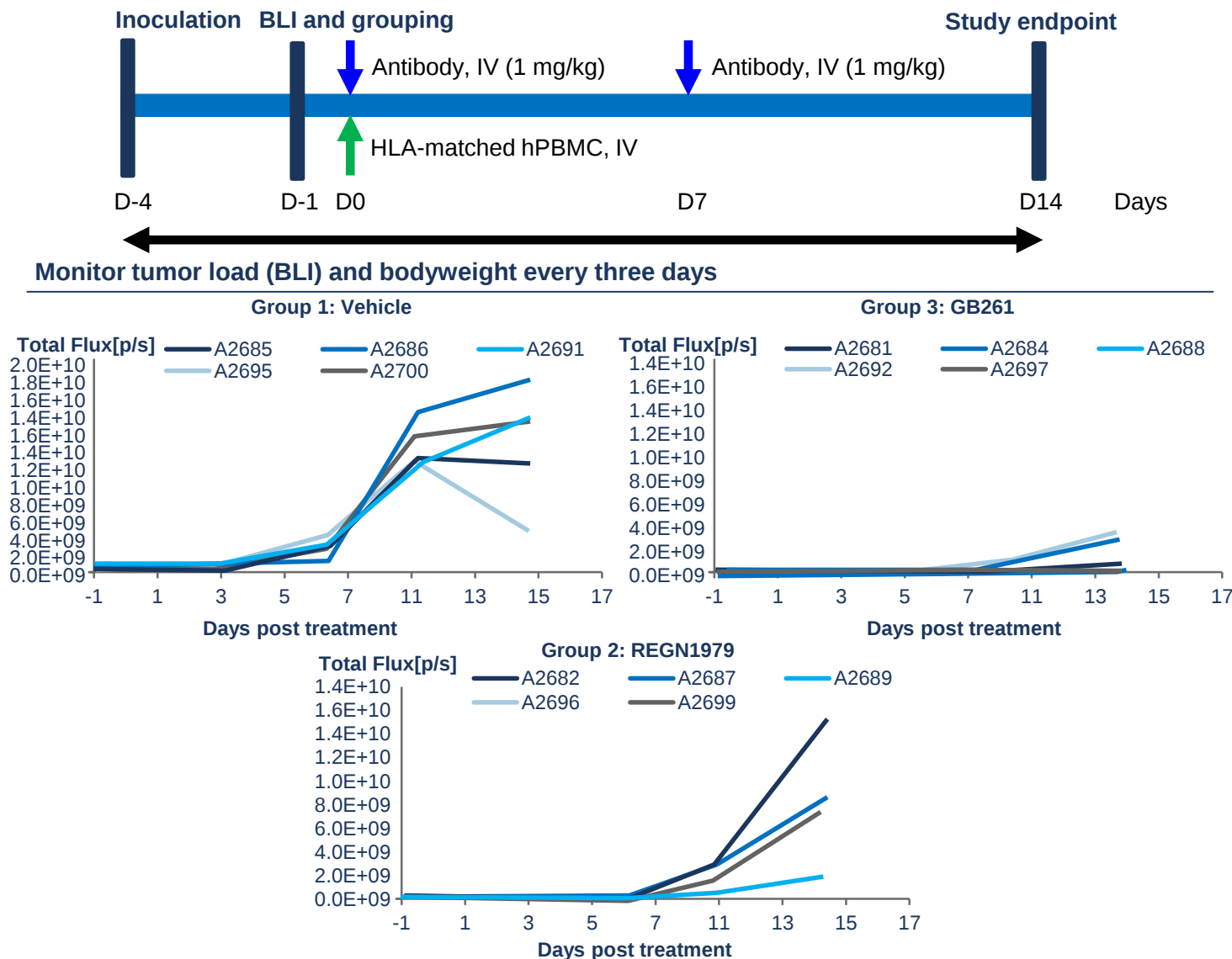


- Induces more Rituxan-resistant Raji cell killing in PMBC-engrafted B-NDG mice
- stimulates less cytokine release



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

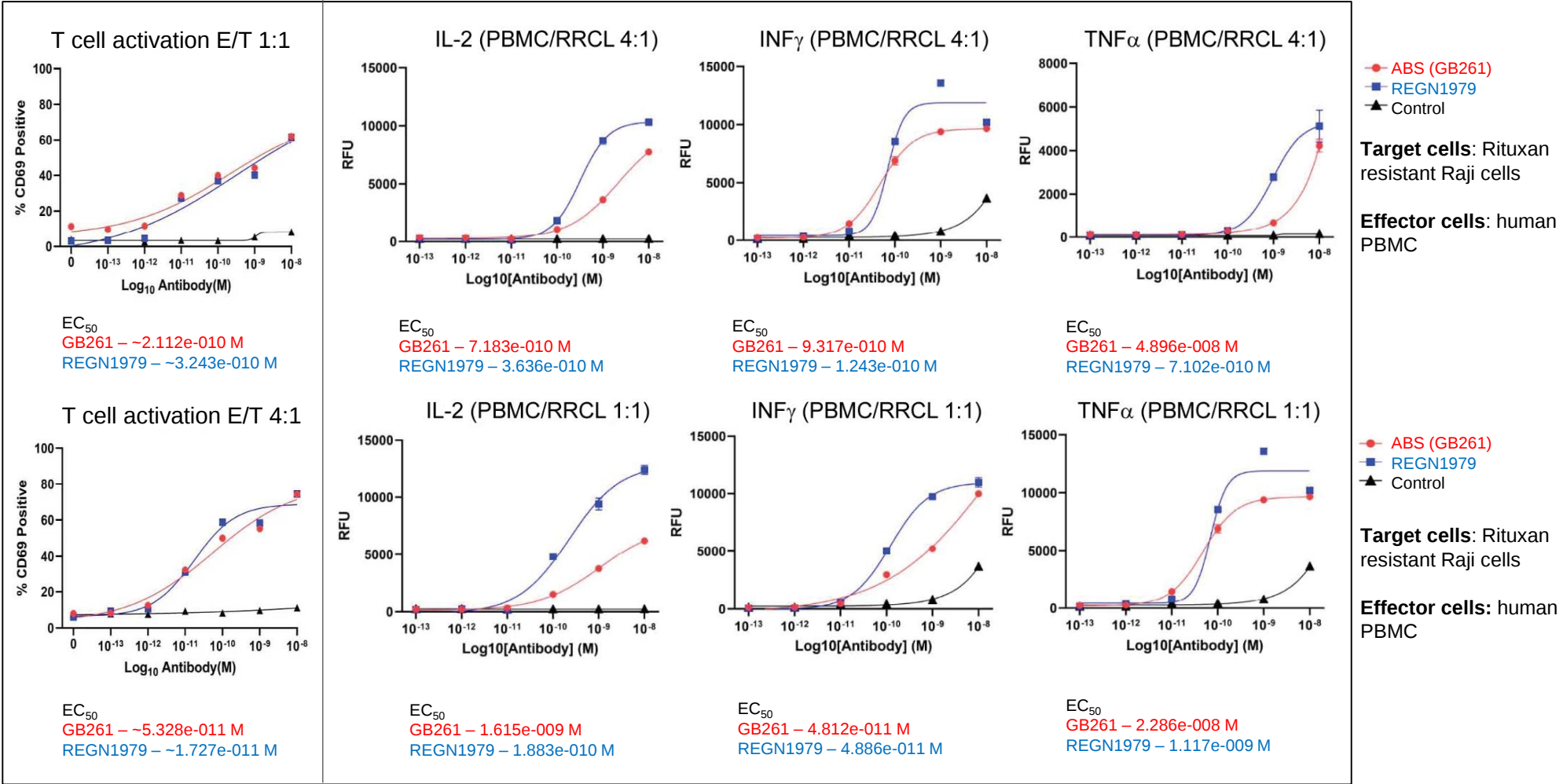
GB261 induces more Rituxan-resistant Raji cell killing in PMBC-engrafted B-NDG mice than REGN1979 analog.





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

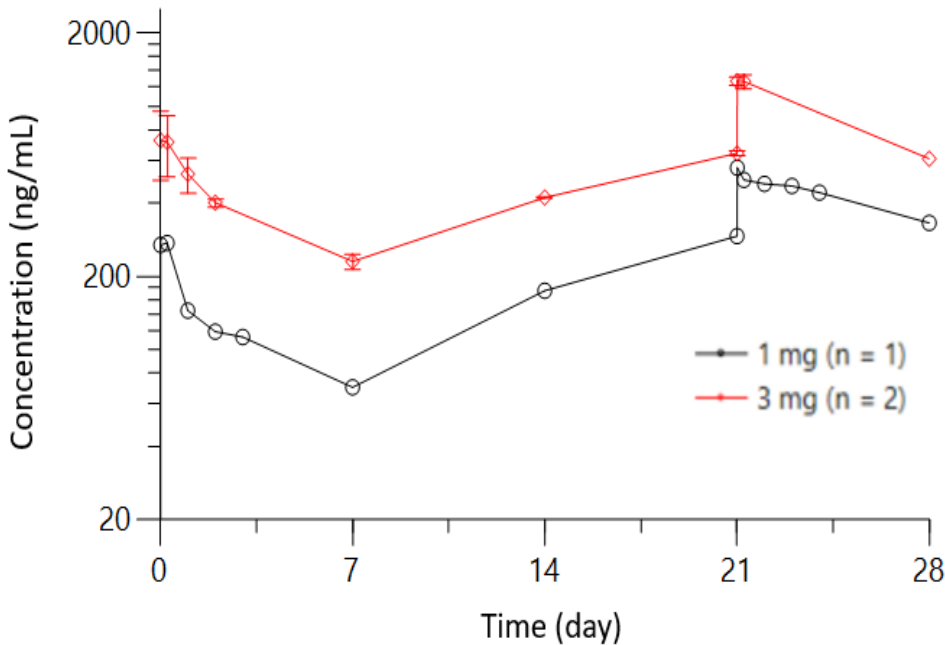
GB261 Clinical Data Conforms to MOA and Pre-clinical Discovery

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

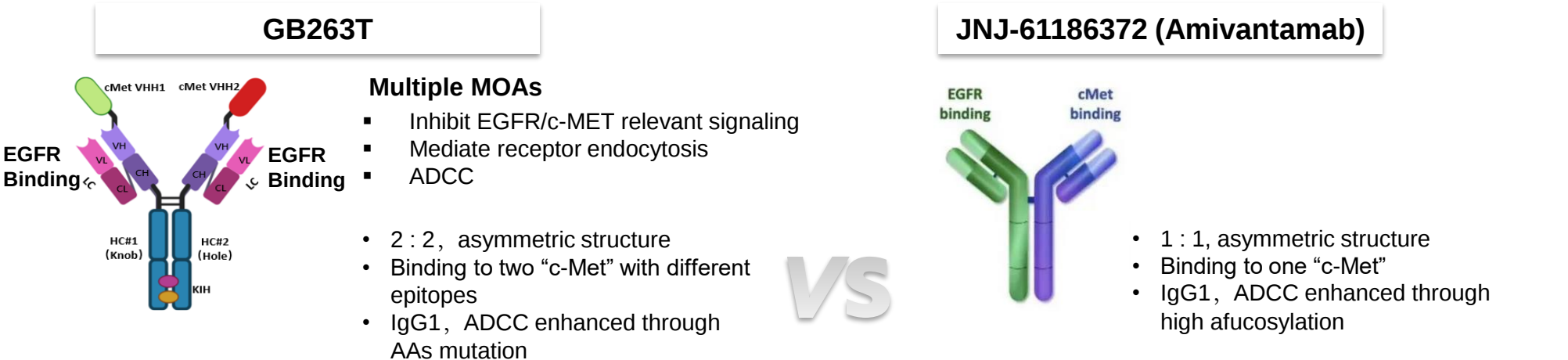
10mg group trial is under way



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





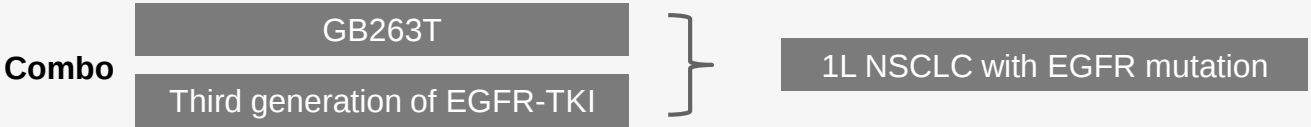
GB263T – Trials in AUS and China



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

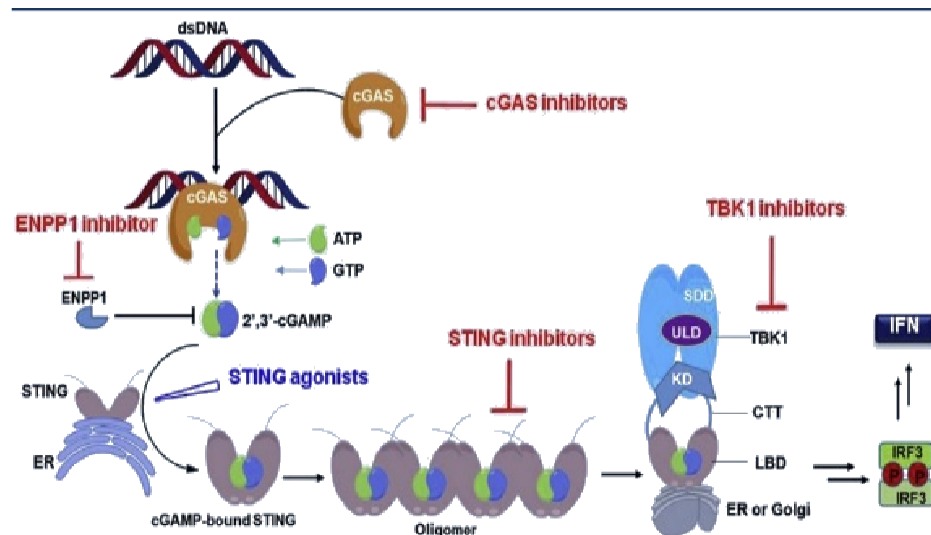




GB492 – A Potentially First-in-class STING Agonist in China

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

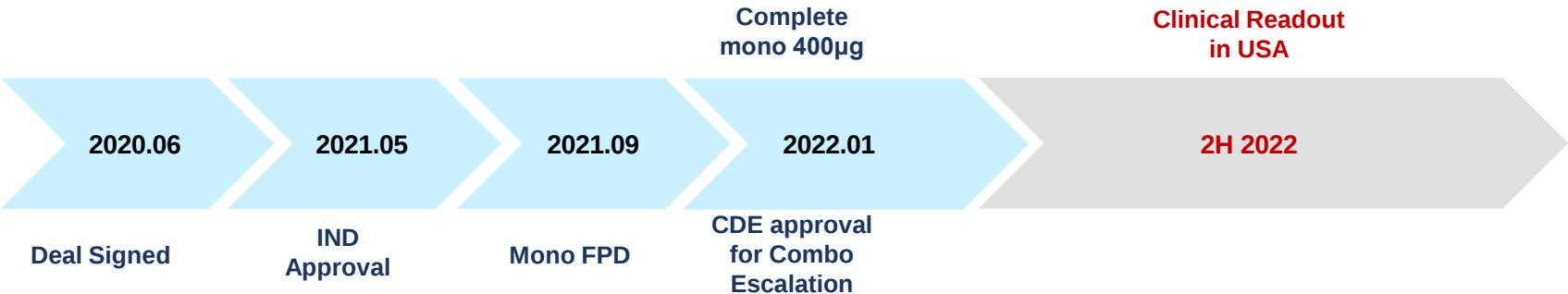
- Preliminary data from Merck's Phase 1 clinical trial for a STING agonist as monotherapy and in combination with Keytruda, in patients with advanced solid tumors or lymphomas
 - The **combination arm had partial responses of 43%** (three out of the seven patients) in HNSCC
 - By contrast, **Keytruda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



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

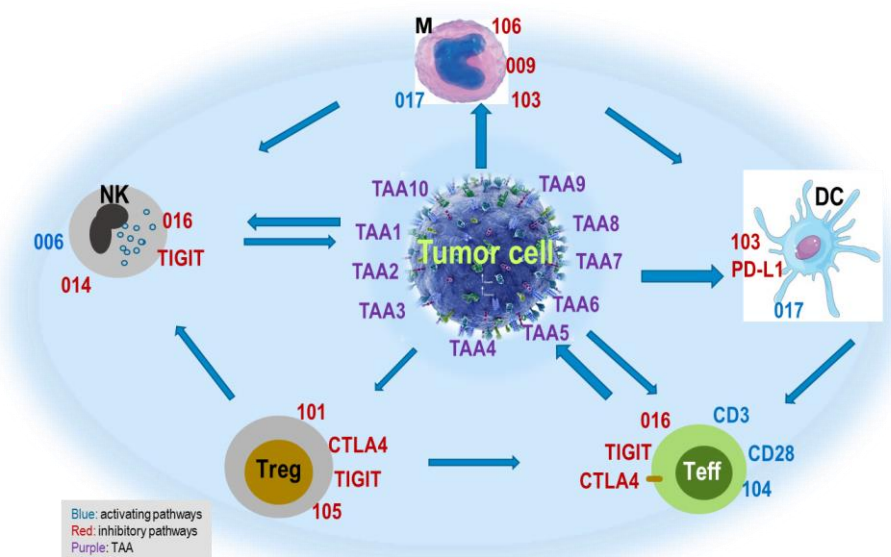
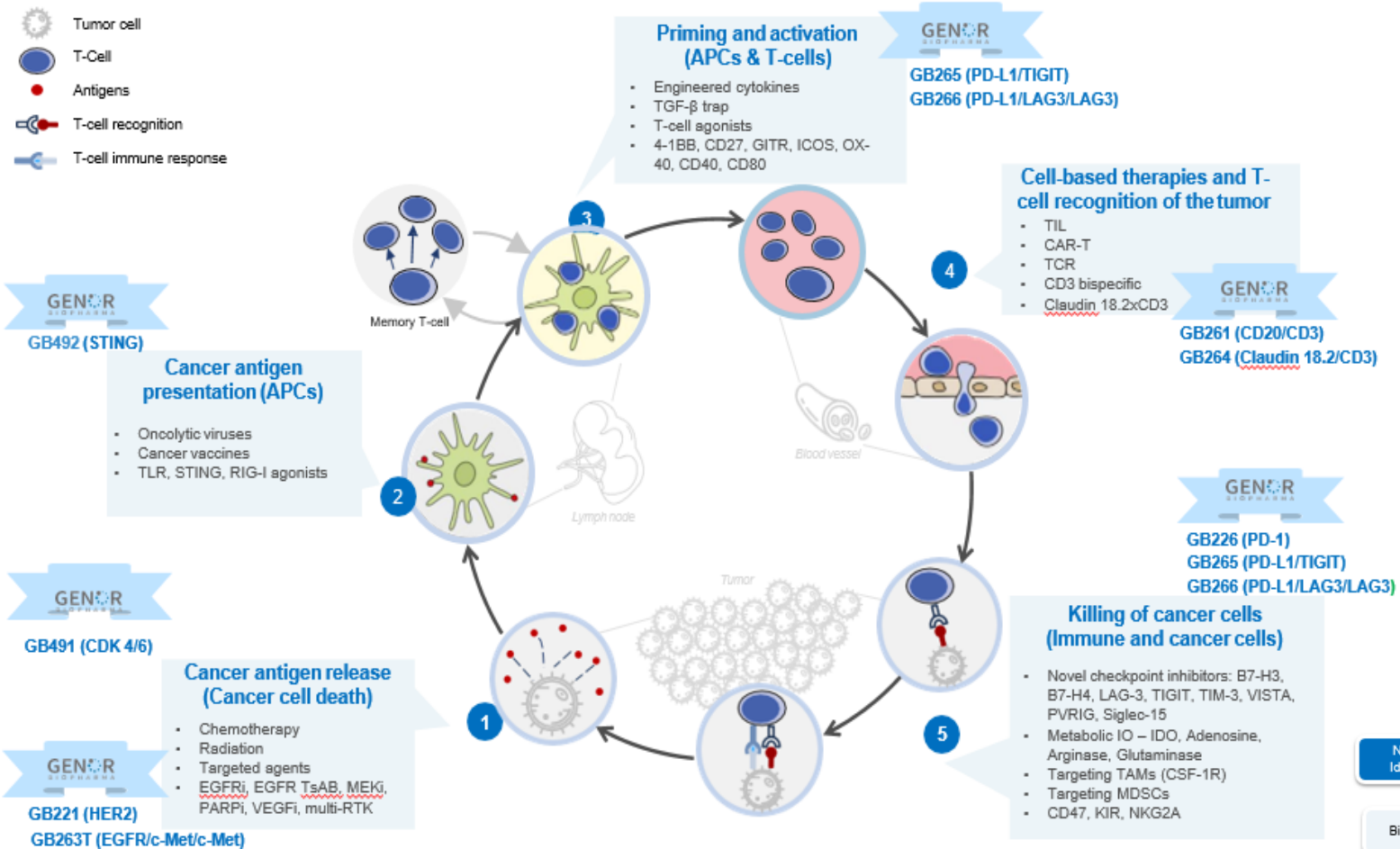


Source: CIC, ESMO



FIC Drug Design Strategy and Integrated Drug Development Platform

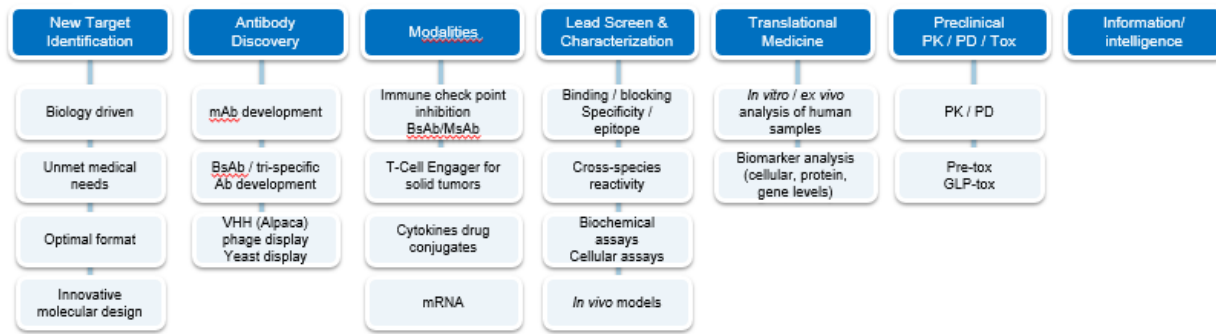
FIC Drug Design Strategy



Focusing on tumor immunology

- BsAb/TsAb
- TCEs
- Cytokines conjugates

FIC Drug Design Platform





New 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

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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)

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

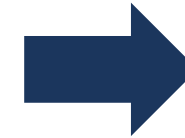
- Net loss for the six months ended 30 June 2022 was RMB 406.6mn

* All numbers are rounded to one decimal place



Financial Overview – Balance Sheet

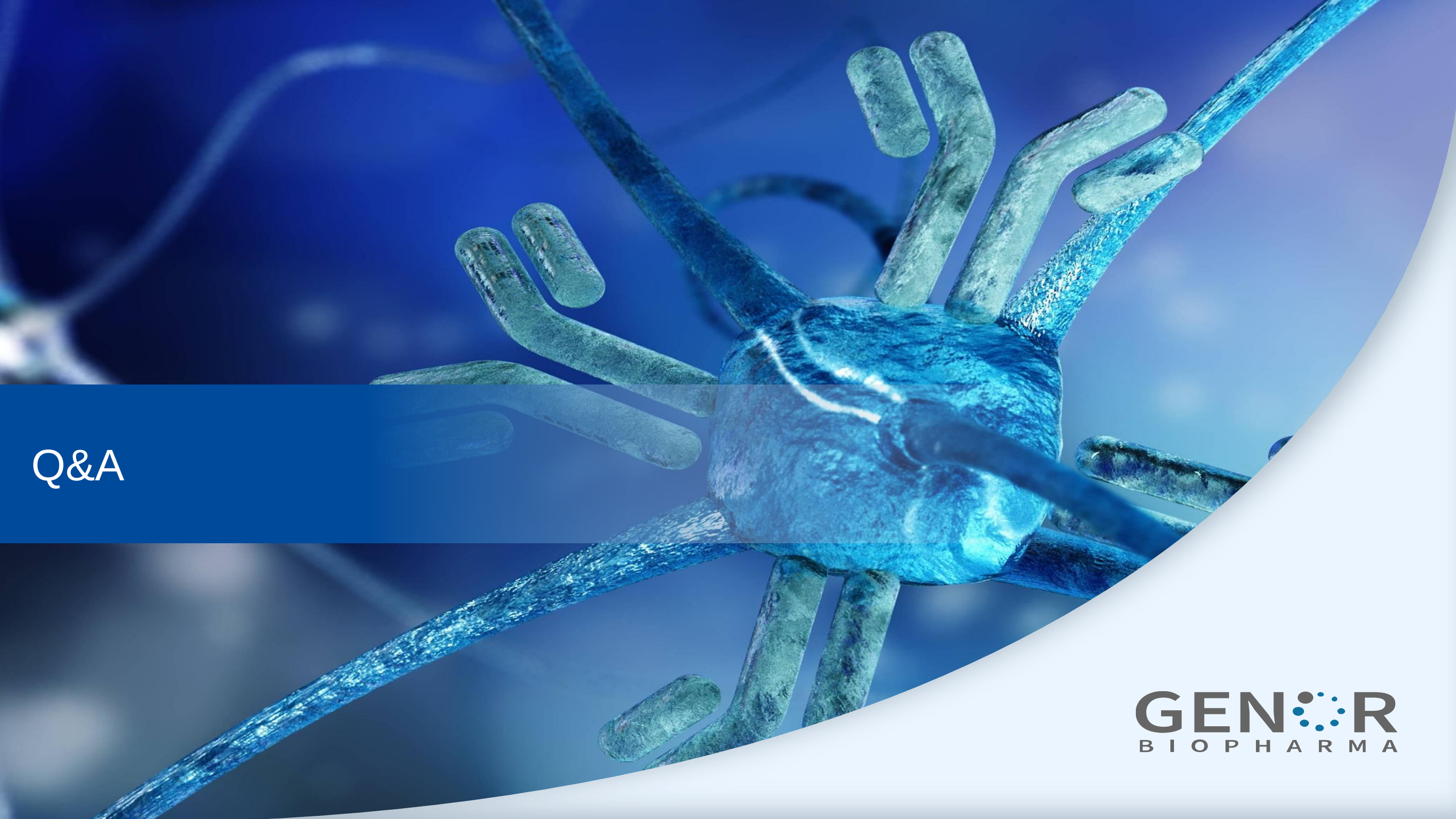
RMB' mn	Jun-22	Dec-21
Cash and cash equivalents	1,858.2	2,200.6
Restricted bank deposits	-	2.0
Inventories	46.5	49.7
Contract cost	1.3	1.8
Other receivables, deposits and prepayments	91.0	132.5
Total Current Assets	1,997.0	2,386.6
Property, plant and equipment	192.2	200.0
Right-of-use assets	51.5	23.3
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



股票代码:6998.HK