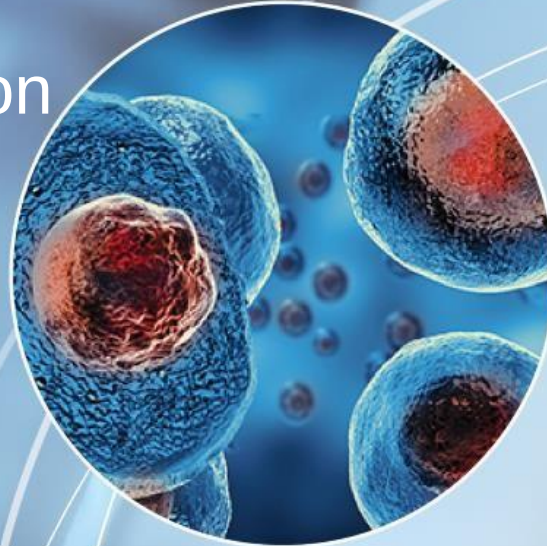


1H21 Interim Results Presentation

August 2021

GENOR
BIOPHARMA



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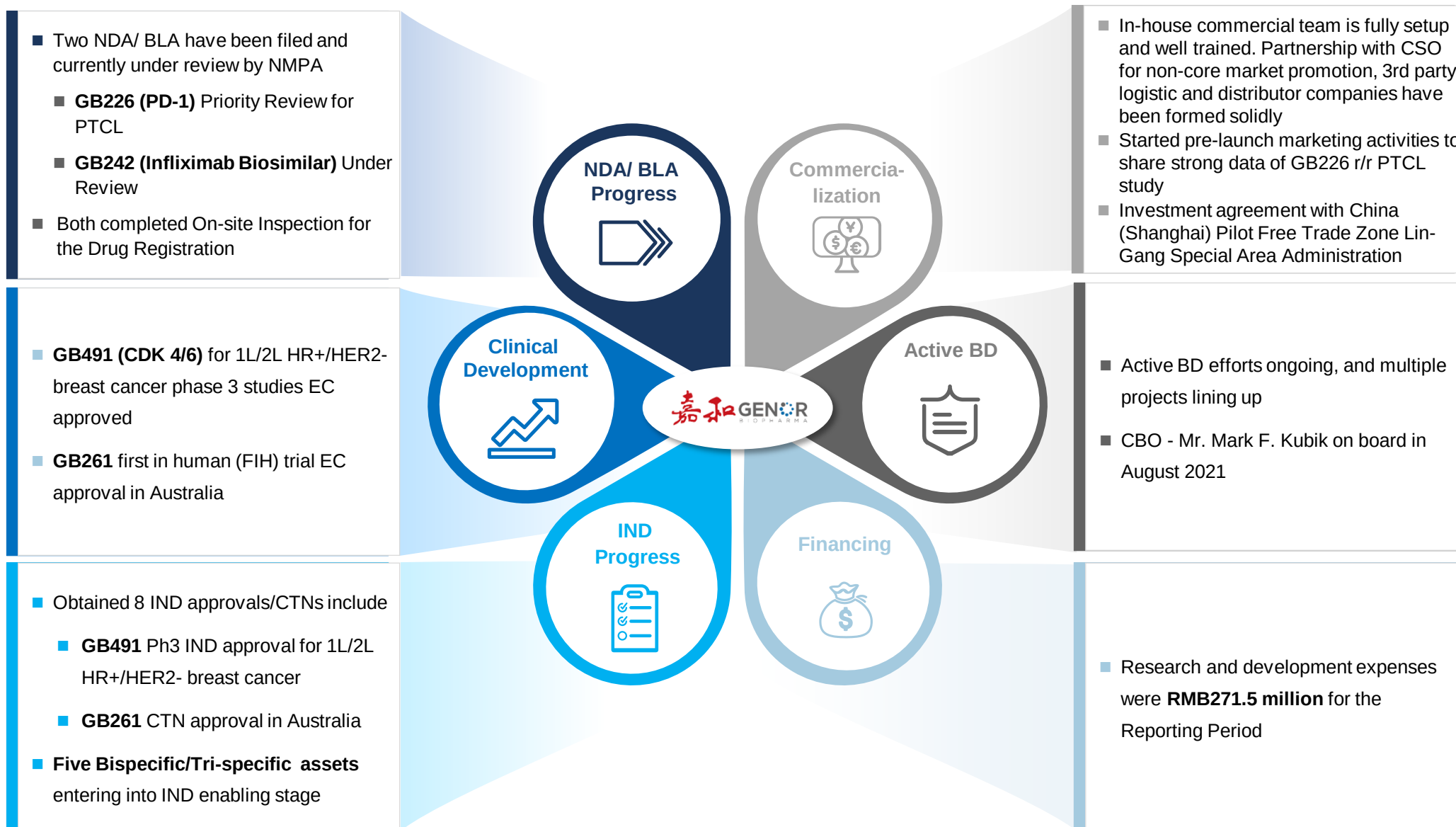
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Agenda





Business Highlights





A Robust Pipeline- Development Stage Assets Focusing on Global Opportunities

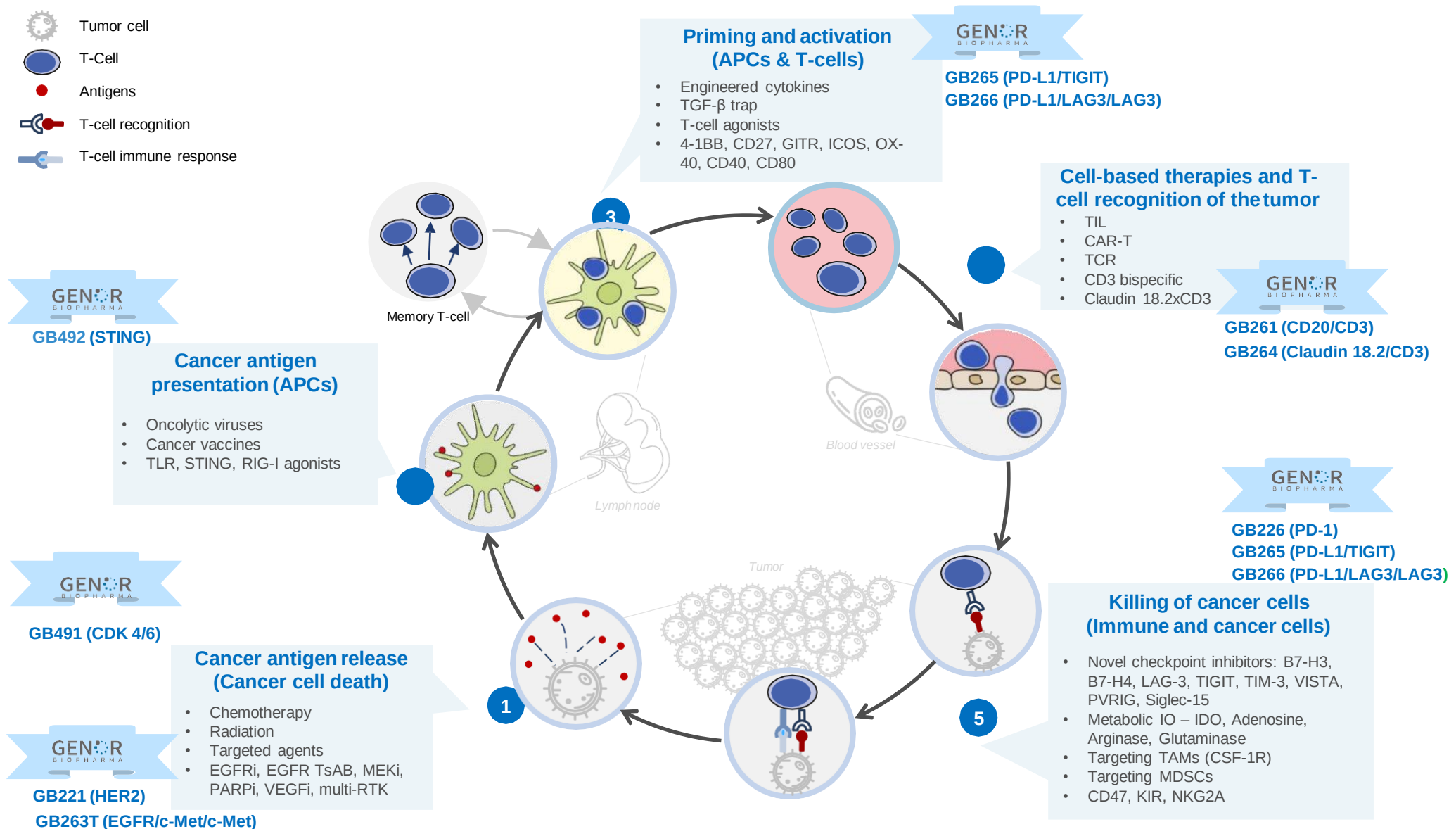
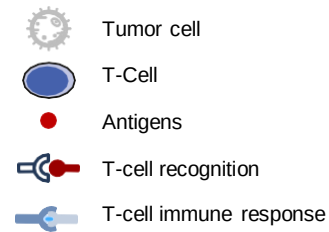
Product	Target/MoA (reference drug)	Indication	Classification	Commercial Rights	Discovery	Pre – Clinical	IND	Phase 1	Phase 2	Phase 3	NDA Filing
GB491	CDK4/6+AI (combo w/ letrozole)	1L HR+/HER2- BC	Novel (In-license)	APAC ex-JP ⁽¹⁾							
	CDK4/6+SERD (combo w/ fulvestrant)	2L HR+/HER2- BC									
	CDK4/6+ EGFR (combo w/ osimertinib)	EGFR-Mutant NSCLC									
GB242	TNF- α (infliximab)	RA, AS, Ps, CD, UC	Biosimilar (In-house)	Worldwide							
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 $\times$ 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							
GB265	PD-L1 $\times$ TIGIT	Cancers	Novel (In-house)	Worldwide							
GB266	PD-L1 $\times$ L.AG3 $\times$ LAG3	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; * six undisclosed candidates in discovery stage



Portfolio Strategy Centered Around the Cancer-Immunity Cycle

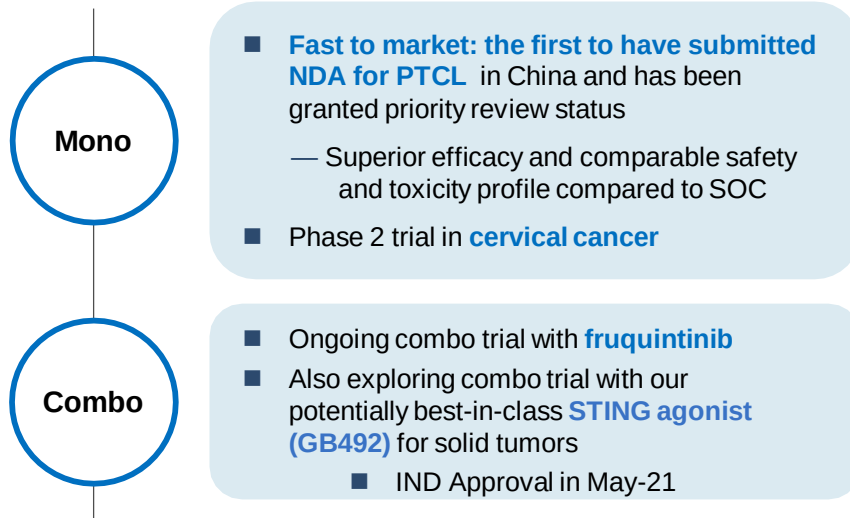




GB226 – Overall Strategy to Maximize Product Value

NDA accepted in July 2020, under priority review

Differentiated clinical strategy in mono and combo therapies



Actively advancing clinical trials in various indications in China

Product	Indication	Phase
GB226	r/r PTCL	NDA under priority review
	2L+ Cervical Cancer	Phase II (Pivotal)
	ASPS	Phase II
	r/r PMBCL	Phase II
	2L/3L+ EGFR+ NSCLC	Phase Ib
GB226+fruquintinib (VEGFR)	2L+ mCRC	Phase Ib
GB226+GB492 (STING)	Solid Tumours	IND approval in May-21 Phase I/IIa ¹

Integrated strategy to drive GB226 launch success



Innovative sales model – establish capable in-house sales with CSO partnership to drive customer coverage and expedite patient penetration while launch



Build fundamental brand awareness in PTCL and selected other tumor segments through making insightful brand strategy and strong execution of marketing activates



Develop integrated access strategy to improve patient affordability for GB226 nationwide



Develop combo therapy strategy with other product is another key driver to maximize GB226 market opportunity, e.g. with EGFR TKI, STING, and BsAb



Commercialization manufacturing capabilities based in Yuxi, Yunnan with excellent quality and enhanced cost efficiencies

¹ GB492 (IMSA101) is currently undergoing a phase 1 trial by ImmuneSensor Therapeutics in the US and we plan to evaluate GB492 in combo with GB226 in China



GB226 provided an attractive treatment option in relapsed/refractory Peripheral T-cell Lymphoma (r/r PTCL) patients

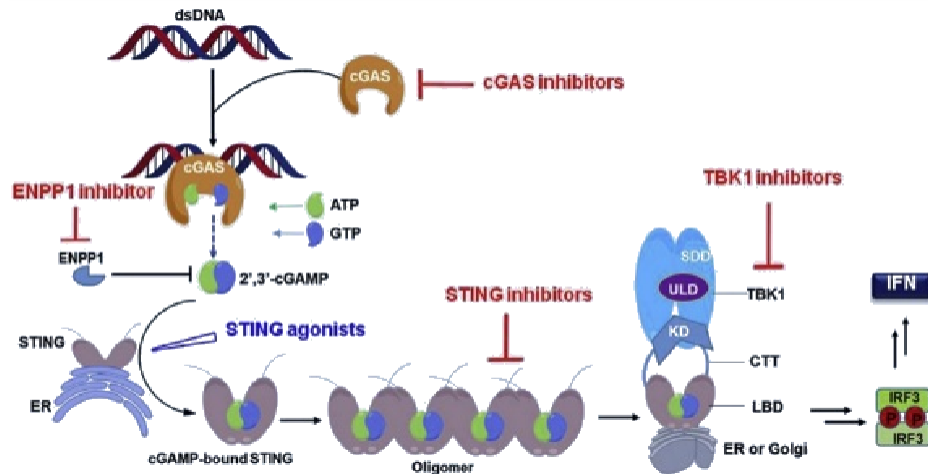
Highly Unmet Medical Needs	r/r PTCL is a very aggressive disease with a median OS of less than one year for patients who failed first line therapy. The newly approved therapy didn't improve overall patients' survival in the past decades.
New MOA	The first IO treatment in r/r PTCL, provided new feature with durable clinical benefit and good safety profile
Competitive ORR	- Independent Review Committee (IRC) assessed ORR: 39.7% (95%CI: 28.45%, 51.86%) - Major r/r PTCL subtypes showed clinical benefit including the very aggressive subtypes (ALCL ALK- ORR: 53.8%, ENKTL ORR: 64.7%)
Sustainable Clinical Benefit	According to IRC, the median DOR is over 18 months among those patients with confirmed response, nearly twice of existing therapies
Clinical Benefit in multi-line failure patients	For r/r PTCL patients who failed Chidamide, the ORR reached 37.5%
Good Safety and Tolerability	Much lower hematological and gastrointestinal toxicities compared with other approved r/r PTCL regimens



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

IND Approval in May 2021

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)

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

Multiple studies show that STING agonist may be used as a new immune stimulatory therapy

Maximum percentage change from baseline in target injected (Enestic) vs. Non-injected (Anenestic) lesions

PRELIMINARY RESULTS OF THE FIRST-IN-HUMAN (FIH) STUDY OF MK-1454, AN AGONIST OF STIMULATOR OF INTERFERON GENES (STING), AS MONOTHERAPY OR IN COMBINATION WITH PEMBROLIZUMAB (PEMBRO) IN PATIENTS WITH ADVANCED SOLID TUMORS OR LYMPHOMAS

Date
20 Oct 2018

Session
Poster Discussion session - Developmental therapeutics / investigational immunotherapy

Presenters
Kevin Harrington

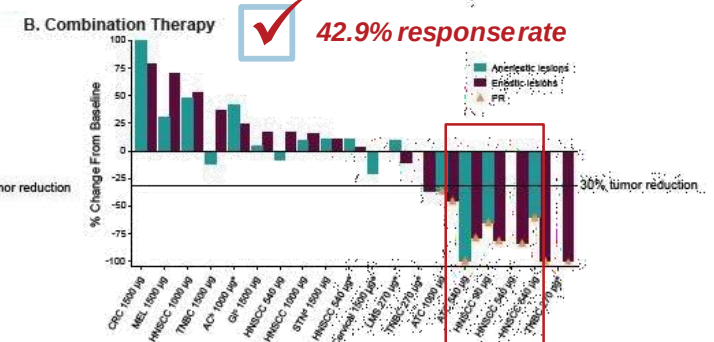
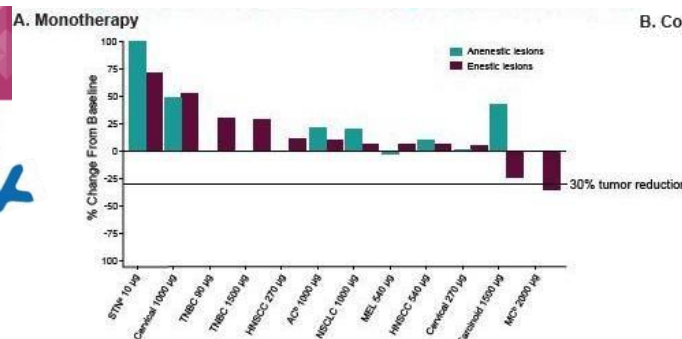
Authors
K.J. Harrington¹, J. Brody², M. Ingham³, J. Strauss⁴, S. Cemerik⁵, M. Wang⁶, A. Tse⁷, A. Khilani⁸, A. Marabette⁹, T. Golani¹⁰

Author affiliations
More

Resources

MERCK

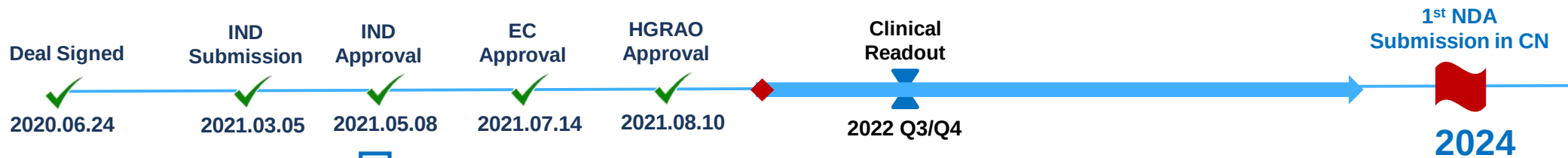
Abstract 5475



Source: CIC, ESMO



GB492 – Preliminary Timeline



- **IND Approval** for an innovative FIH trial Design combining 2 dose escalation in one study
 - GB492 mono
 - GB492 + PD-1 combo
- Start the dose-escalation from 400ug in China vs. 100ug in the US



Pivotal Studies in multiple tumor types



Note: US completed 1200ug and also start combo escalation after 800ug dose-cohort completed

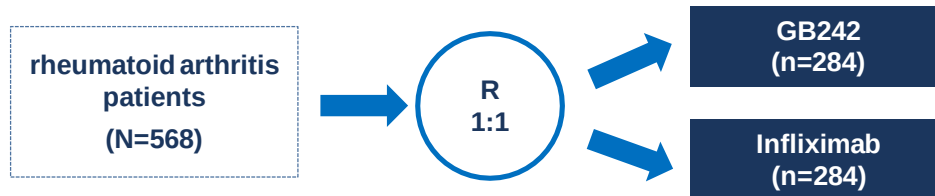


GB242 – Substantial Market Expansion for Autoimmune Diseases

NDA Filed in November 2020 Expecting Approval in the First Half of 2022

GB242 – Infliximab biosimilar

Phase 3 Study completed, NDA under review



Remicade has the most extensive indications approved in China among TNF-α

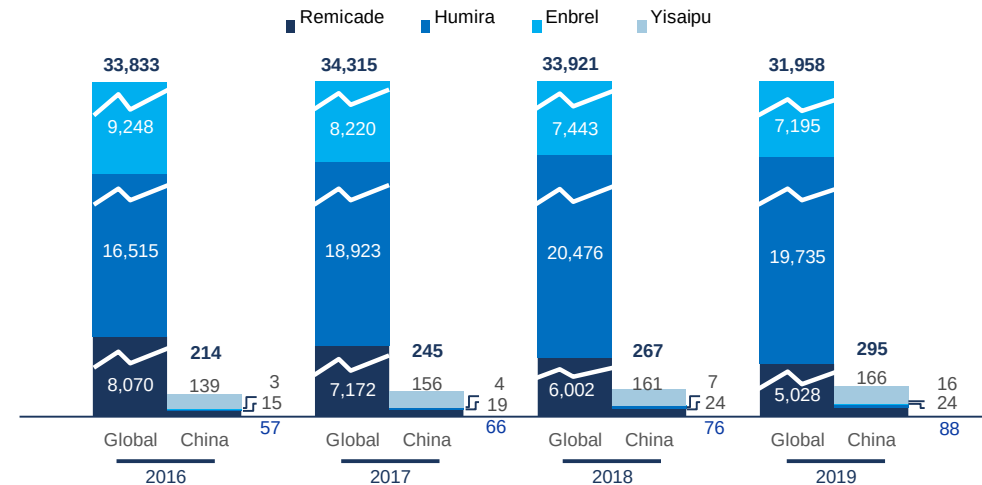
Brand Name	Generic Name	Company	Approval**	Indication
Yisaipu	Etanercept	3SBio	2005	RA, AS, Ps
Remicade	Infliximab	JNJ	2006	RA, AS, Ps, CD, UC
Humira	Adalimumab	AbbVie	2010	RA, AS, Ps, CD, UV
Enbrel	Etanercept	Pfizer	2010	RA, AS
Anbainuo	Etanercept	Hisun	2015	RA, AS, Ps
Simponi	Golimumab	Janssen Biologics	2017	RA, AS
Cimzia	Certolizumab	UCB	2019	RA
BAT1406	Adalimumab	Bio-Thera	2019	RA, AS, Ps, CD, UV
HS016	Adalimumab	Hisun	2019	RA, AS, Ps, CD, UV

Assets to address autoimmune market

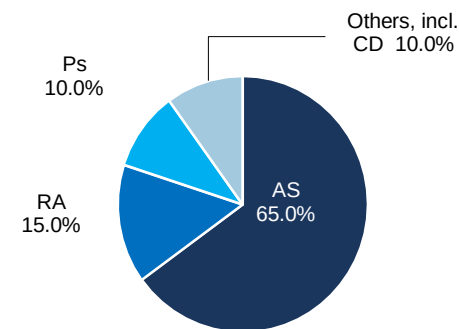
Product	Target indication	Target	Patient Size	Recruitment Status	Type of Therapy	Phase
GB242	RA, AS, Ps, CD, UC	TNFα	568	Enrollment completed	With MTX	3

Significant market expansion expected

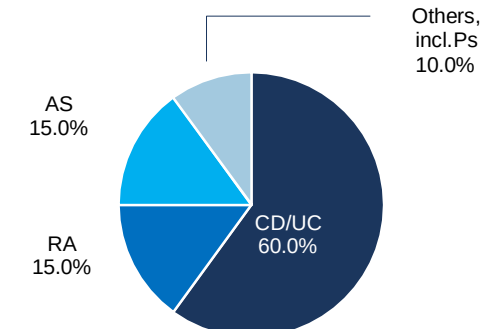
US\$m



Humira's sales distribution in China



Remicade's sales distribution in China



Abbreviations: RA=Rheumatoid Arthritis, AS=Ankylosing spondylitis, Ps=Psoriasis, CD=Crohn's disease; UC=Ulcerative Colitis

Source: Evaluate pharma, annual reports, CDE, China Insights Consultancy, public filings; *Aggregate sales for Yisaipu, Remicade, Humira and Enbrel; **CFDA/NMPA approval



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

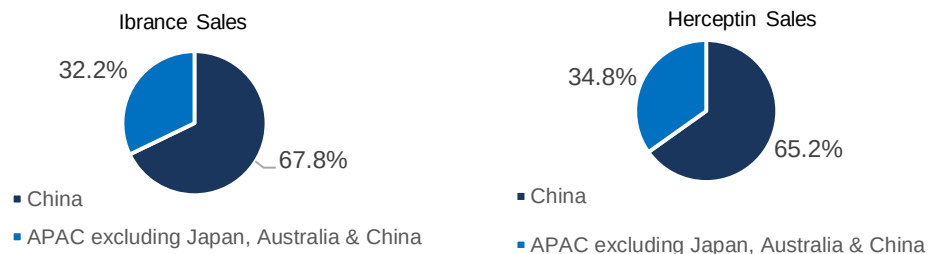
Well-positioned to capture the huge Breast Cancer (eBC & mBC) and HNSCC markets in APAC

- Currently **completing phase 2a trial** in combo with fulvestrant conducted by G1 Therapeutics in the US

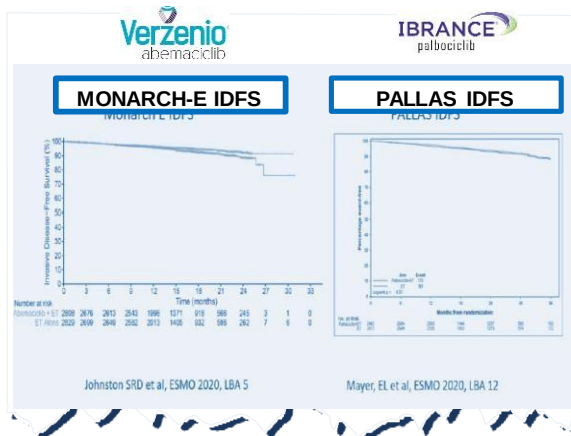
- We plan to **rapidly develop GB491 in HR+/HER2- BC**, with subsequent plans to expand our clinical programs to include **multiple other indications** with novel combinations



≥1.5x Opportunities in APAC* vs. in China only



Verzenio (Eli Lilly)'s successful MONARCH-E study in adjuvant setting eBC



- Continuous dosing** contributed to the success of MONARCH-E compared with intermittent therapy in PALLAS study
- Different** relative effects on CDK4/6
- Fewer drug discontinuations** in MONARCH-E compared with PALLAS (16.6% vs 42.2%)

Company	Drug	China Status	Setting	Registry / Approval Date	Patent Expiry
Pfizer	Ibrance	Launched	1L	Aug-18	Jan-23 ²
Eli Lilly	Verzenio	Launched	1L	Dec-20	Nov-29
Novartis	Kisqali	Phase 3	1L	Aug-18	Aug-29
Hengrui	SHR6390	NDA submission	2L	Apr-21	
Genor	Lerociclib	Phase 3	1L / 2L	Jul-21	
Sihuan	XZP-3287	Phase 3 IND Approval	2L / 3L	Aug-21	
Fosun	FCN-437	Phase 2	1L	Aug-20	
Sino Biopharma	TQB3616	Phase 2	1L	Feb-21	
Beta	BPI-1178	Phase 1/2a	1L / 2L	Feb-20	
Betta	BPI-16350	Phase 1		Jan-19	
BeBetter	BEBT-209	Phase 1		Sep-19	

Source: G1 Therapeutics, FDA, ESMO 2020, PubMed, CIC

¹ RMB1.7bn market is calculated based on roughly 100k HNSCC patients in China in 2030, 70% are HPV-unrelated, 20% penetration rate of CDK4/6 drugs, and roughly RMB120k annual price

² Potential extension to 2028; * 2018 APAC Sales Data excluded Japan and Australia



GB491 (Lerociclib) – Superior Efficacy Profile & Better Tolerability

Higher ORR vs. Palbociclib in Paloma-3 Trial

	Lerociclib Phase 1/2a (ongoing) ¹	Eli Lilly Monarch-2	Pfizer Paloma-3	Novartis Monaleesa-3
Line setting	Median 2L+	1/2L	1L+ (2L 40%, 3L 25%)	1/2L
Treatment	Lerociclib + fulvestrant	Abemaciclib + fulvestrant	Palbociclib + fulvestrant	Ribociclib + fulvestrant
ORR	31.6%	48.1% vs. 21.3%	24.6% vs. 10.9%	32.4% vs. 21.5%
CR	0	3.5% vs. 0	NA	1.7% vs. 0
PR	31.6%	44.7% vs. 21.3%	NA	30.8% vs. 21.5%
SD	47.4%	34.3% vs. 51.2%	NA	33.3% vs. 34.3%
DCR²	79.0%	82.4% vs. 72.6%	NA	65.7% vs. 55.8%
mPFS	28.6 mo	16.4 vs. 9.3 mo	9.5 vs. 4.6 mo	20.5 vs. 12.8 mo

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; CIC; ESMO 2020; Bisi J. E., Sorrentino J. A., et al; Oncotarget. 2017; 8: 42343-42358; Ping Chen, Nathan V. Lee, et al; Mol Cancer Therapeutics. October 1 2016 (15) (10) 2273-2281; DOI: 10.1158/1535-7163.MCT-16-0300; Dickler et al, Clin Cancer Res; 2017; Notes: ¹ 150mg BID group; ² DCR=CR+PR+SD.

Source: G1 Therapeutics, FDA, ESMO 2020 poster; data cutoff: 17 Apr 2020
Note ¹: for 150mg BID dosing group



GB491 (Lerociclib) – Clinical & Regulatory Pathway in China

Global Phase 2 trial is ongoing (2L Advanced BC)

3-mon tox study

Commercial formulation

Ph3 clinical supply

Ph3 protocol

Pre-IND & IND

- Completed all the activities required for Ph3 IND in 12 months

- Global Ph2 trial is ongoing with Ph1/2 clinical formulation

2L Advanced Breast Cancer (GB491 + Fulvestrant)

IND for Ph1b

Phase 1b bridging study
Waived

IND for Ph3

Phase 3 registration trial
(270 subjects)

Imported NDA by 4Q23

1L Advanced Breast Cancer (GB491 + Letrozole)

IND for Ph1b

Phase 1b bridging study
(10-16 subjects)

IND for Ph3

Phase 3 registration trial
(270 subjects)

Imported NDA by 2Q24

Tech Transfer & Local Manufacturing

Tech Transfer & DOE
for local manufacturing

PV batch production
and stability study

Local Manufacturing
NDA by 4Q24/1Q25

China
development
and
regulatory
pathway

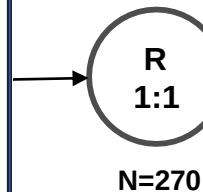


GB491 (Lerociclib) – Clinical Trial Design in China

Phase III GB491-004 Trial Design for 2L Advanced Breast Cancer

Key Eligibility Criteria:

- HR+ /HER2- Advanced Breast Cancer
- Pre/Perimenopausal or Postmenopausal ^a
- Relapsed on or within 1 year from completion of adjuvant ET with no subsequent ET received
- Relapsed >1 year from completion of adjuvant ET and then subsequently relapsed after receiving first-line ET
- Presented de novo disease and progressed on first-line ET
- No more than one line of chemotherapy for advanced disease



GB491 150mg BID PO
+
Fulvestrant 500mg Q4W IM ^b

Placebo BID PO
+
Fulvestrant 500mg Q4W IM ^b

Primary Endpoint:

- Investigator-assessed PFS

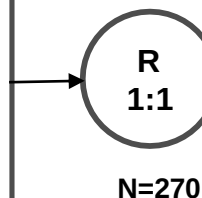
Secondary Endpoints:

- BIRC-assessed PFS
- OS
- ORR, DOR, CBR
- AE/SAE
- PK

Phase III GB491-005 Trial Design for 1L Advanced Breast Cancer

Key Eligibility Criteria:

- HR+ /HER2- Advanced Breast Cancer
- Pre/Perimenopausal or Postmenopausal ^a
- No prior systemic therapy for advanced disease
- Relapsed >1 year from completion of adjuvant ET with no subsequent ET received
- Presented de novo disease and no prior ET



GB491 150mg BID PO
+
Letrozole 2.5mg QD PO or

Placebo BID PO
+
Letrozole 2.5mg QD PO

Note:

a. Goserelin should be administered Q4W only for pre/perimenopausal subjects.

b. Fulvestrant should be administered on C1D1 & C1D15, then Q4W from C2D1.

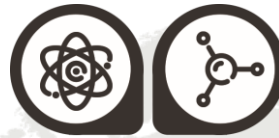


Global Leading Antibody Discovery Platform & Strong CMC Capabilities

Advanced Innovative Discovery Platform with Addition Advantage Enabled by Speed and Cost


Global Leading Powerful Discovery Platform for BsAb/MsAb

Select innovative and proven Targets



Exploring the pharmacological mechanism based on clinical data



To build manufacturing facility in Lin-Gang



Advanced Technology

Utilize CAAD and optimized Knobs-into-Holes design to develop significantly differentiated bi-specific/tri-specific antibody drug candidates

Select drug candidates with the best designed pathway to ensure drugability and optimal speed for development



Powerful pre-clinical candidates under pipeline with multiple bi-specific/multi-specific candidates expected to file dual IND in China the US



Strong CMC capabilities and commercial-ready continuous-flow cell culture technologies enabling us manufacture product with low costs and high speed

Differentiated Bi-specific/Multi-specific Candidates under Pipeline - Overcoming the Refractory Tumor

GB261

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

- Target for hemangioma
- T cell activation
- Less cytokine release

GB262

PD-L1/CD55, the first BsAb induces both T cell activation and CDC

- Targeting a variety of solid tumors, including pancreatic cancer

GB263T

The First TsAb of EGFR/cMET/cMET Targeting NSCLC

- Target for EGFR-TKI resistant NSCLC

GB264

A Highly Differentiated Claudin 18.2/CD3 for GI Cancers

- Target for the treatment of gastric and pancreatic cancer

GB265

A bi-specific antibody candidate targeting PD-L1 and TIGIT

- Targeting a variety of cancers

GB266

A first-in-class tri-specific antibody of PD-L1/LAG3/LAG3

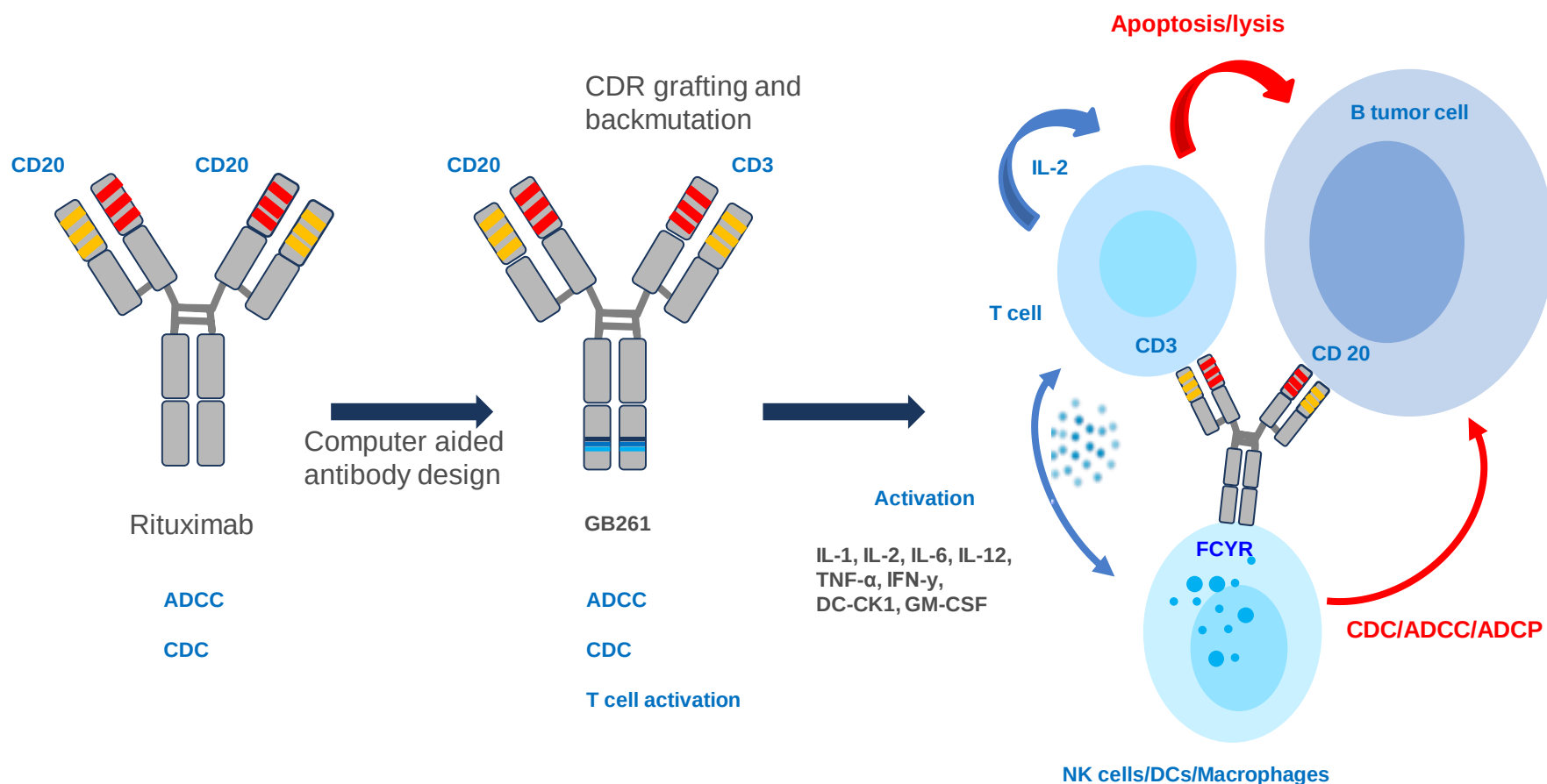
- Targeting a variety of cancers

+ 6 novel targets under discovery



GB261 – A Highly Differentiated CD20xCD3 BsAb for B-cell Lymphoma

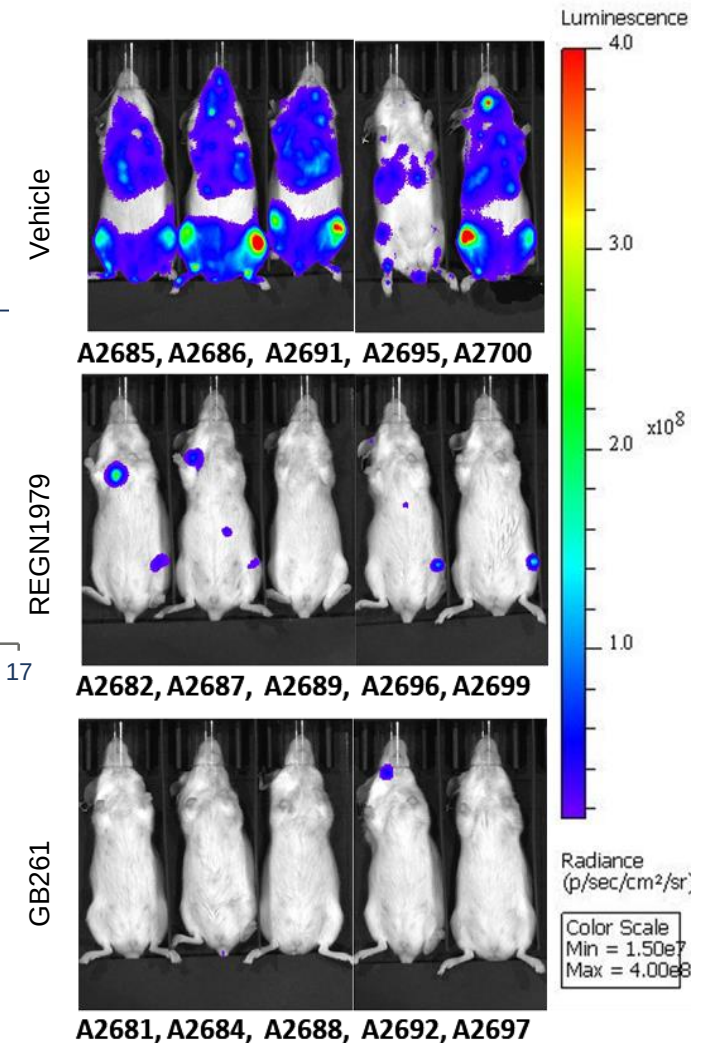
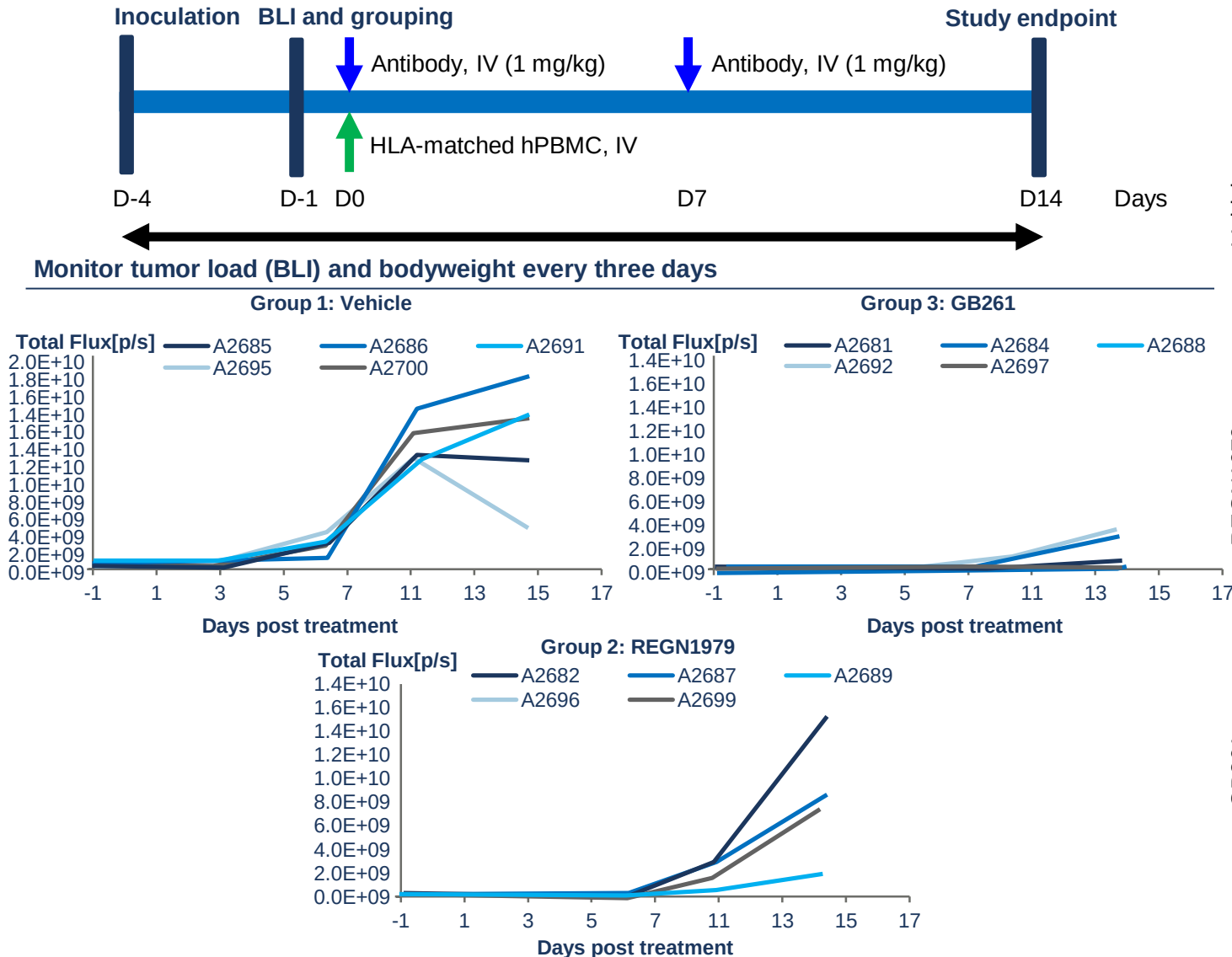
The first T-cell engager with super low CD3 binding affinity and maintaining Fc effector functions (ADCC and CDC) , rendering better safety and multiple mechanisms to better kill cancer cells.





GB261 significantly inhibits rituximab-resistant tumor growth (in vivo)

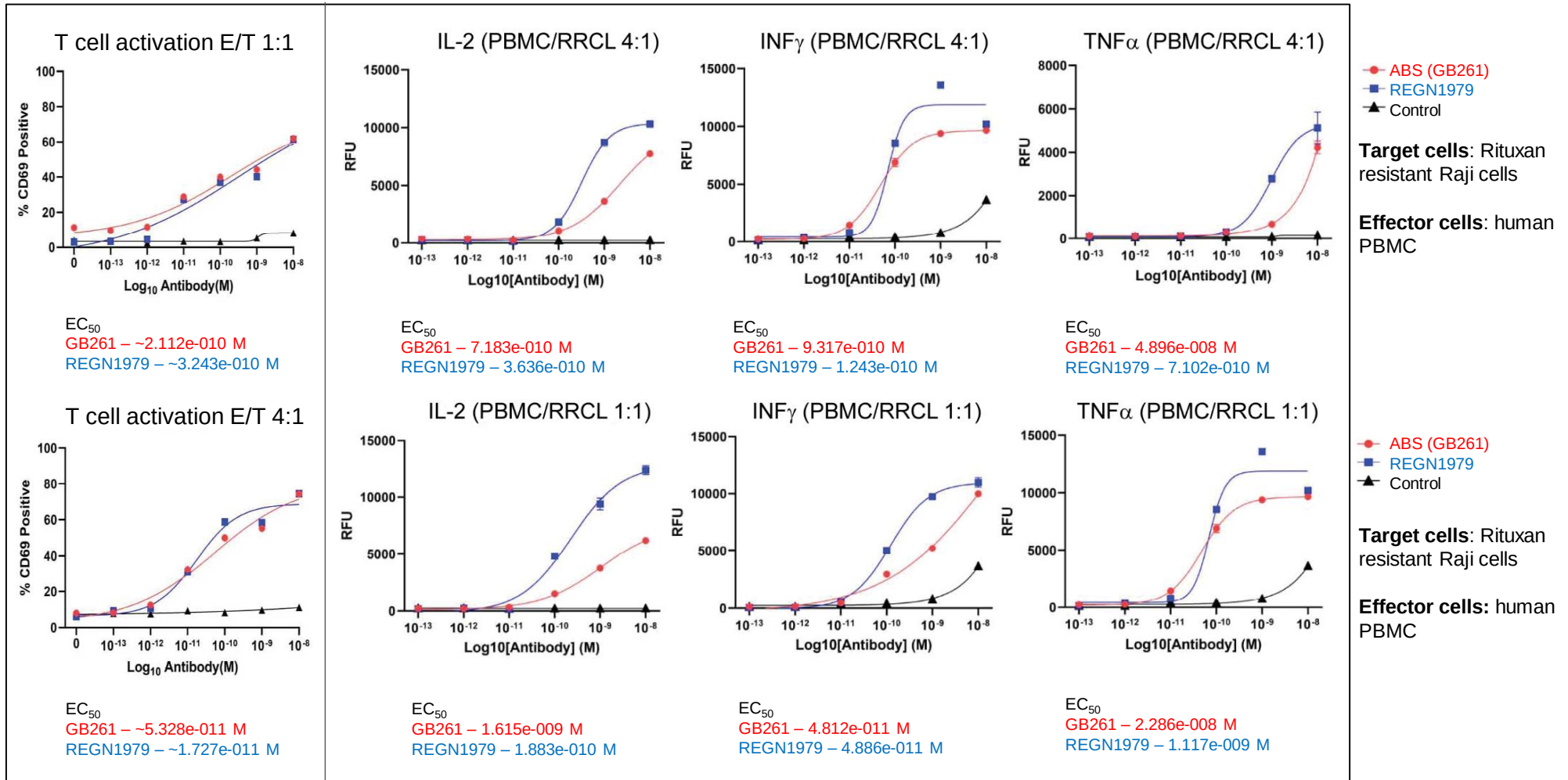
GB261 induces more Rituxan-resistant Raji cell killing in PMBC-engrafted B-NDG mice than REGN1979 analog.





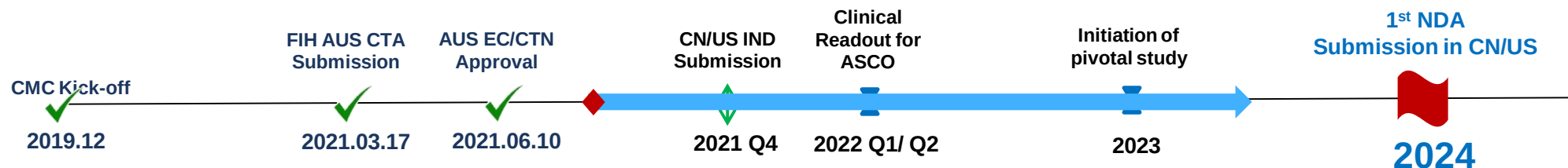
GB261 induces T cell activation with less cytokine releases

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





GB261 – Preliminary Timeline



Clinical Development and Regulatory Plan

- Plan to file IND in China and the US after initial clinical data available in AUS
- Same protocol for three countries without lowering starting dose
- The titer achieved ~6g/L at fed-batch mode

Fast to Market Strategy (Preliminary)

Single-Arm Trials in
CN/US/AUS

R/R FL

R/R DLBCL

MCL

R/R B-NHL

Large Indication Strategy

1L DLBCL* &
Other Indications

GB261 + PD-1 + SOC

GB261 + SOC

*Target NDA approval in 2025/2026



GB261 Ph1 Design - Optimized Dose Escalation and Expansion

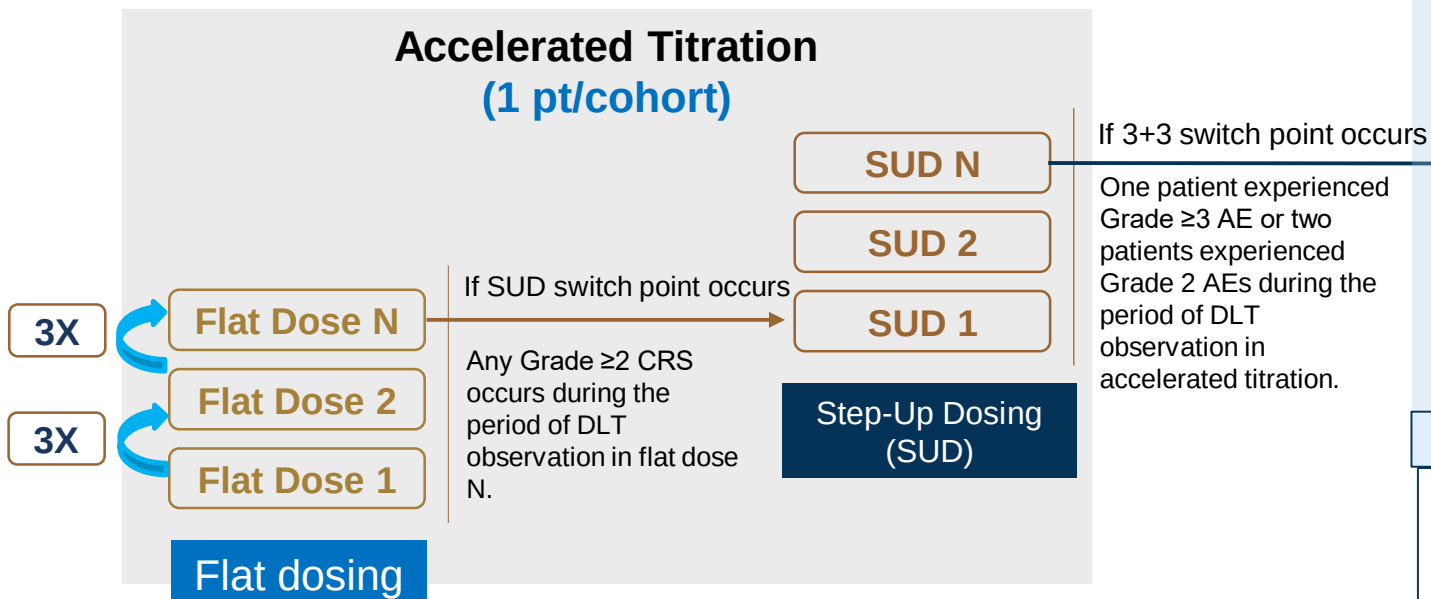
Candidates	GB261	Mosunetuzumab (RG7828)	Odronextamab (REGN1979)	Glofitamab (RG6026)
Starting Dose	1mg	50µg	30 µg	5 µg

Optimized escalation method:
accelerated titration + standard titration

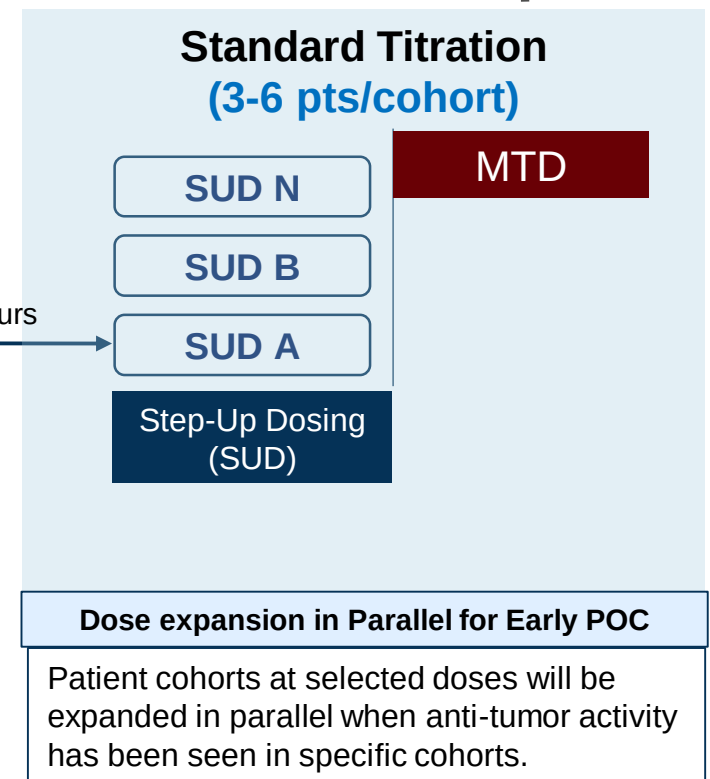


- Undertreated patient number ↓
- Speed to effective dose range ↑
- Close monitoring and careful management of safety ↑

Accelerated Titration (1 pt/cohort)



Standard Titration (3-6 pts/cohort)





GB263T – the First TsAb of EGFR/cMET/cMET Targeting NSCLC

MOA Introduction

- Project Mission: Best in class therapeutic Ab targeting both EGFR & cMET pathways
- Promote therapeutic efficacy on TKI resistant NSCLC
- Expanding therapeutic objective window on NSCLC by co-targeting EGFR (both wild-type and mutant EGFR) and C-Met expressing tumor cells
- Design the multi-specific antibody with great safety, efficacy and manufacturability balance
- Built-in new internalizing MOA for better targeting signal transduction pathways involving EGFR/EGF and C-Met/HGF



3rd generation TKIs:
osimertinib (TAGRISSO) and
rociletinib

1st generation TKIs: gefitinib and erlotinib
2nd generation TKIs afatinib and
dacomitinib

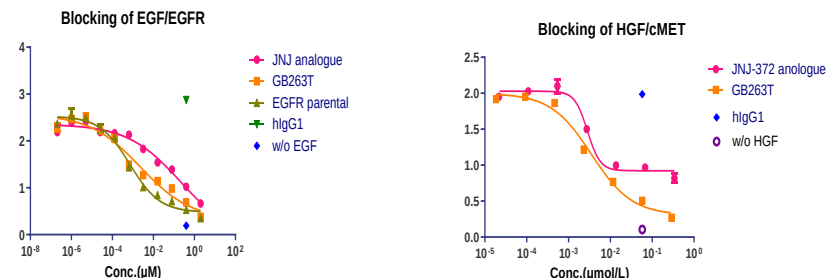
In addition to secondary **EGFR mutations**, bypass mechanisms such as **MET** or **ERBB2 amplification**, Hippo pathway inhibition, and insulinlike growth factor 1 receptor (IGF1R) activation also contribute to resistance to EGFR-TKIs

Market Analysis

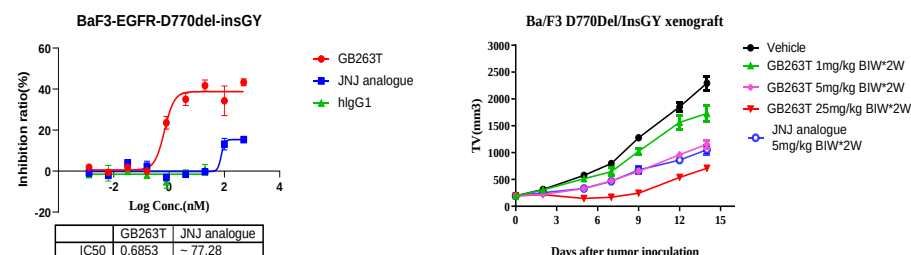
First TsAb designed which binds to two different epitopes on cMET and one on EGFR resulting in enhanced internalization of the receptors and suppression of cancer cell proliferation. TsAb also shows enhanced cancer cell death

Project Highlights

- **GB263T shows better activity than JNJ analogue to block EGFR/EGF or cMET/HGF binding**



- **GB263T inhibits EGFR-exon20ins cell proliferation and tumor growth in vivo**

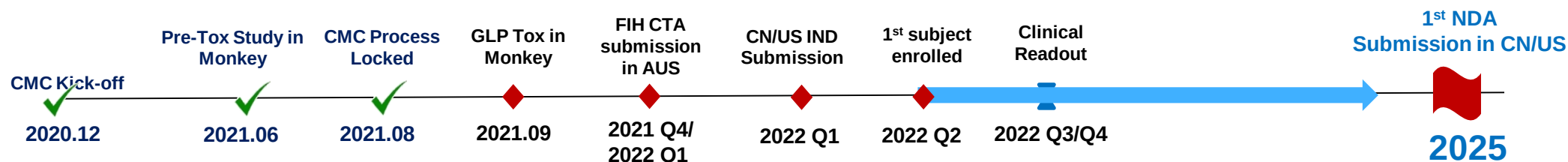


Summary

- GB263 tri has shown enhanced potential in internalizing into cancer cells that express cMET/EGFR.
- GB263 tri has shown potent blocking of EGF/HGF ligand binding
- GB263T inhibits EGFR-exon20ins cell proliferation and tumor growth in vivo



GB263T – Preliminary Timeline



CMC Process

- High titer of ~7g/L achieved

Fast to Market Strategy (Preliminary)

Single-Arm Trials in CN/US/AUS

Monotherapy for EGFR exon 20ins, post chemo

Ph3 Trial Strategy

1L EGFR exon 20ins NSCLC

EGFR mut NSCLC, post-osi

1L 19del or 21 L858R subs NSCLC

*Target NDA approval in 2027/2028

GB263T + Chemo

GB263T + 3GTKI + Chemo

GB263T + 3GTKI



GB264 – A Highly Differentiated Claudin 18.2xCD3 for GI Cancers

Background

- Claudins are important components of the tight junctions that control flow of molecules in the intercellular space between epithelial cells
- Claudin18.2 is highly expressed in gastric and pancreatic adenocarcinoma
- Its restricted expression makes Claudin18.2 a potential target for the treatment of gastric and pancreatic cancer

Project Rationale

Designing a T cell engaging Bispecific antibody that targets Claudin18.2 expressing cancer cells with great safety, efficacy and manufacturability balance

Market Analysis

Approximately one million new cases of Gastric (stomach) cancer are diagnosed worldwide each year with five-year survival is ~5–20%

Project Highlights

Differentiation

- Better safety/efficacy balance
 - Lower T cell binding [Solve Safety Issue]
 - Enabled cancer specific Fc effector function (ADCC/CDC) [Benchmark does not]

Results

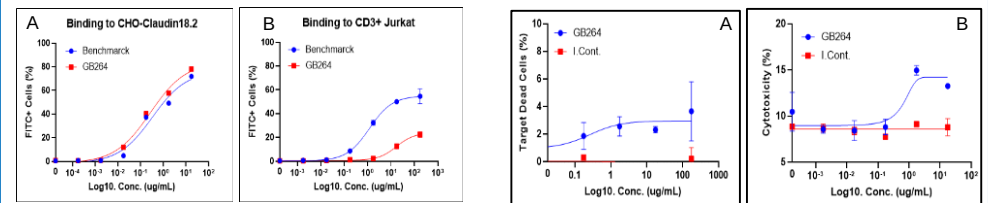


Fig 1. GB264 has similar binding ability to Claudin18.2+ cells compared to that of benchmark (A) and significantly lower binding ability to CD3+ cells compared to BM (B).

Fig 2. GB264 specifically induces ADCC (A) and CDC (B) on Claudin18.2+ target cells.

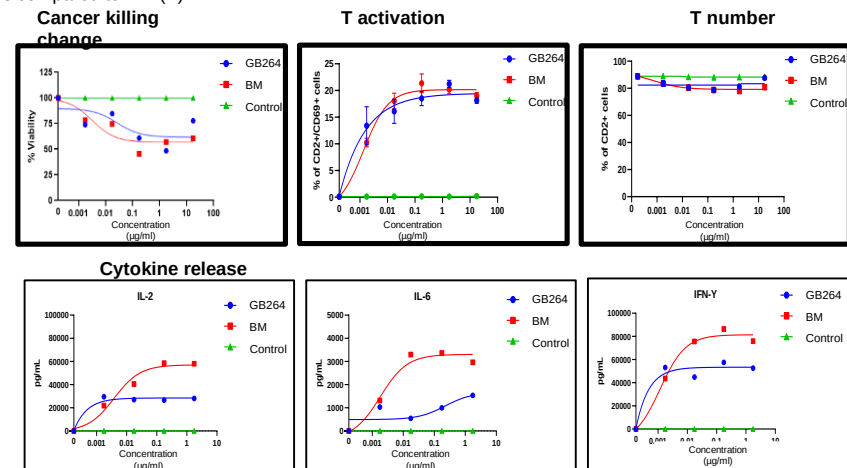


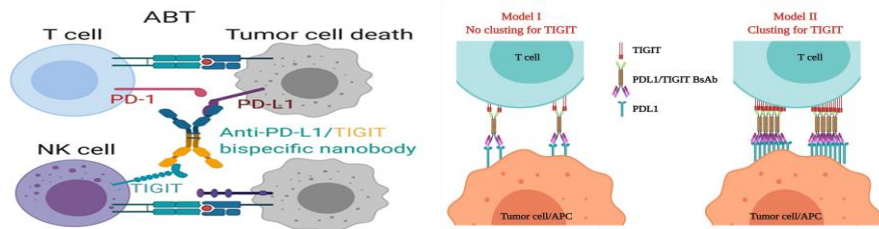
Fig 3. At E/T 5 to 1, GB264 has comparable cancer killing, T activation and less cytokine release compared to that of BM



GB265 – PD-L1xTIGIT

MOA Introduction

- Project Mission: developing therapeutic bispecific antibodies targeting PD-L1/TIGIT pathways
- PD-1(programmed death protein 1) and TIGIT ((T cell immunoreceptor with Ig and ITIM domain), suppress T cell effector function, resulting in abolished anti-tumor immunity.
- Blocking their binding to PD-L1 or CD155 on tumor cells can unleash immune cells functions against tumors.
- PDL-1/TIGIT Bispecific antibodies bind to two targets simultaneously to redirect both tumor cells and immune cells close together
- to enhance cytotoxicity efficacy and induce the generation of cells cluster with stable immunological synapse and potential paracrine cascade against tumor cells.
- The rationale is to induce superior tumor immunity compared to monospecific antibodies



Summary

- GB265 (PD-L1/TIGIT BsAb) can bridges cancer cell and T cell and leads to the clustering of Ab-Ag complex at the interface of the two cells
- GB265 might have sufficient efficacy
- AFF huD4 showed increased TIGIT binding ability
- GB265 BS2 promotes human T cell activation
- GB265 structure with Fc effector function retained has ADCC function

Project Highlights

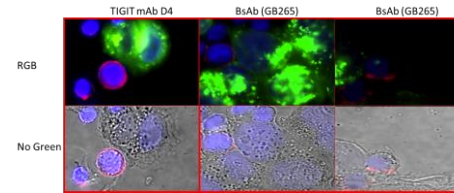


Figure 1: IF data suggests GB265 can bridge PD-L1 positive cancer cells and TIGIT positive Jurkat-TIGIT cells.

Red: TIGIT
Green: tumor cells
Blue: Jurkat-T or NucleuS

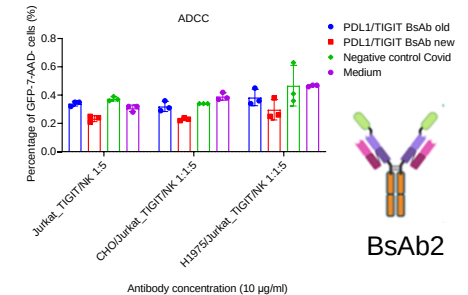


Figure 2: GB265 structure BsAb2 with Fc effector function retained ADCC function

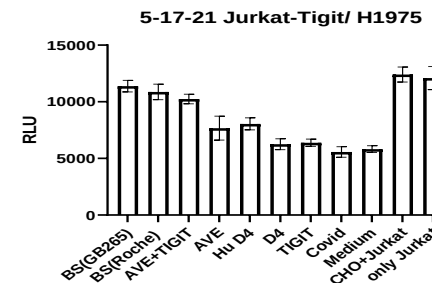


Figure 3: in vitro Luc reporter assay data suggests that GB265 could activate TIGIT stably transfected Jurkat cell in the presence of PD-L1 positive cancer cells.

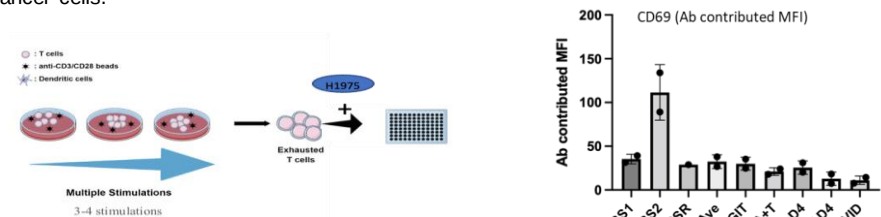


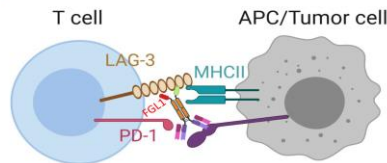
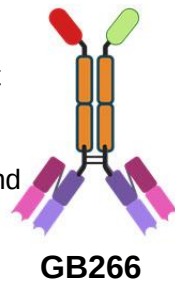
Figure 4: Coculture of day7 human exhausted T cell and cancer in the presence of GB265BsAb2 (with Fc effector function) leads to the best T cell re-activation.



GB266 – First Tri-specific Antibody against PD-L1 and LAG3

MOA Introduction

- PD-1 and LAG3 are the most promising immune checkpoint proteins
- Project Mission: Best in class therapeutic Ab targeting both PD-L1 & Lag3
- Promote therapeutic efficacy on PD-L1 inhibitor resistant cancer patients
- Simultaneously block the interaction of Lag3-MHC II, FGL1-Lag3 and PD-L1/PD1 with great safety, efficacy and manufacturability balance
- Built-in new clustering MOA for better activating T cell function



Current ABT GB266 lead:

- Block PD-L1/PD-1 interaction
- Block Lag3/MHCII interaction
- Block Lag3/FGL1 interaction

First TsAb against PD-L1/Lag3. It can simultaneously block the interaction of Lag3-MHC II, FGL1-Lag3 and PD-L1/PD1. In vitro studies show GB266 is more efficacious than the benchmark

Summary

- H3 is a blocker for MHC II-Lag3 interaction. H3 has a stronger Lag3 binding capacity in cell-based assays than the benchmark and a similar blocking ability to the benchmark.
- B7 is a blocker for the FGL1-Lag3 interaction. B7 has a better Lag3 binding capacity in cell-based assays than the benchmark.
- Lead GB266 is more efficacious than the Benchmark and FS118 in luciferase-based T cell activation assays.
- Lead GB266 is more potent in inducing T cell activation in PBMC than the benchmark.

Project Highlights

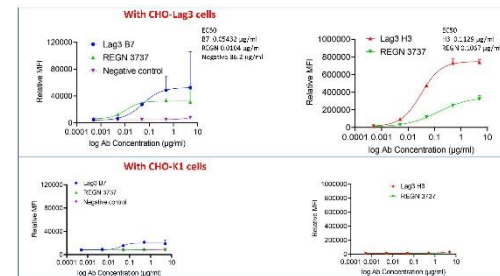


Fig 1. A) Lag3 antibodies B7 and H3 have stronger binding capacities to CHO-Lag3 cells than Regn3767. **B)** B7 and H3 do not significantly bind to CHO cells

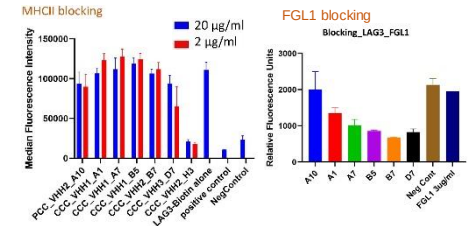


Fig 2. A) H3 strongly blocked Lag3 binding to the endogenous MHCII in Raji cells. **B)** B7 blocked the FGL1-Lag3 interaction.

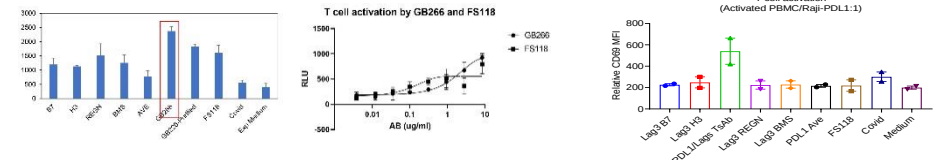


Fig 3. A) Jurkat-Lag3-PD-1 reporter cells were incubated with different antibodies for 30 min, and then LK35.2-PD-L1-MHCII-OKT3- cells were added and incubated for 5 h. T cell activation was determined by luciferase assays. **B)** Dose-dependent T cell activation by GB266 and FS118 determined using the same assays in "A".

Fig 5. Lead GB266 efficiently induces exhausted T cell activation. PBMC was exhausted with CD3/CD28 beads for 7 days before mixed with Raji-PD-L1 cells.

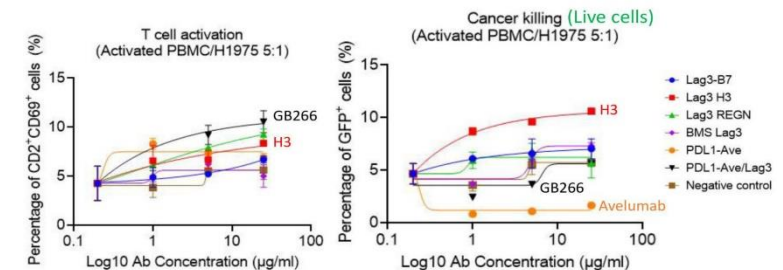
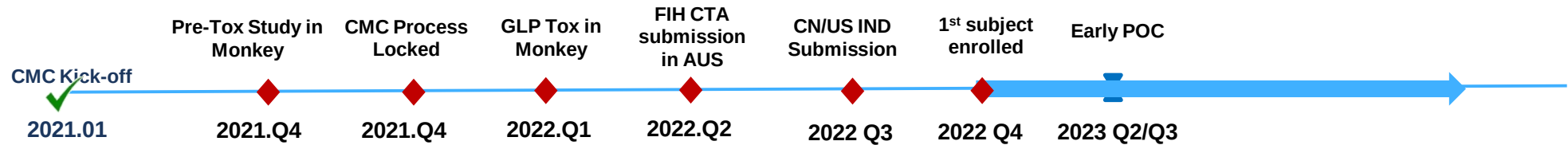


Fig 4. Lead GB266 is more potent in inducing T cell activation in PBMC. Activated PBMC were incubated with H1975-GFP cells and antibodies. T cell activation was determined by CD2-CD69 staining, and cancer cell killing was defined by percentage of live H1975-GFP cells, using FACS.

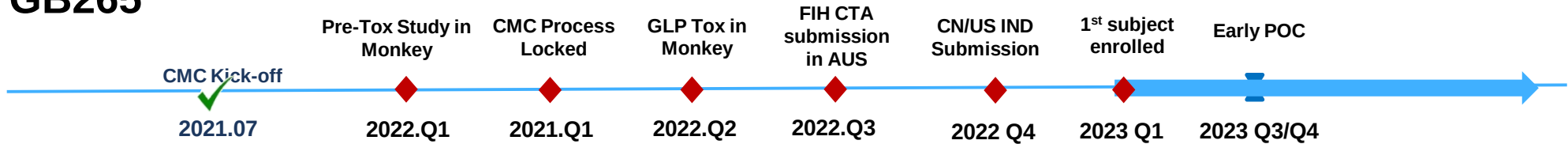


GB264/GB265/GB266 – Preliminary Timeline

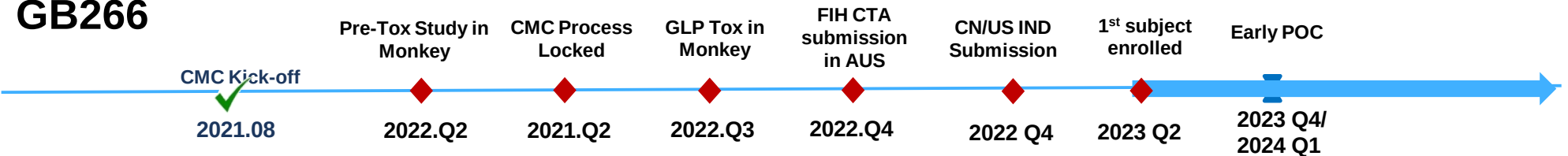
GB264



GB265



GB266





End-to-end Fully-integrated Biopharmaceutical Platform

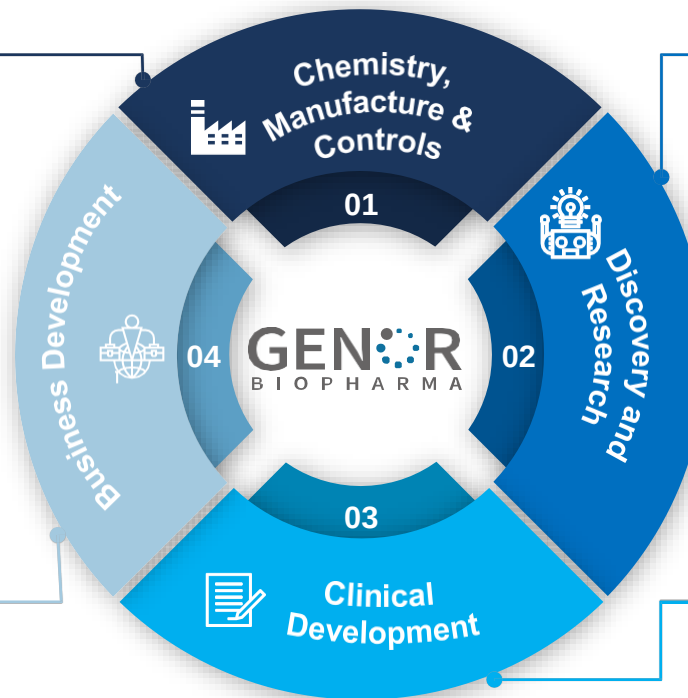
Fully-integrated, end-to-end biological platform encompasses all the key biologic drug development functionalities

- Strong CMC capabilities with extensive international experiences and **one decade of antibody technology development** in China
- **~8,000 m² commercial-ready GMP** manufacturing facility for both pivotal trial supplies and product launches, allowing us to meeting regulatory expectations smoothly
- **Commercial-ready continuous-flow cell culture technologies**, enabling us to manufacture product with **low costs**

- **Proactive and systematic approach** to evaluate assets for in-licensing opportunities
- **A proven track record** of collaborating with biopharmaceutical and biotechnology companies across the globe



- Benefitting from the global network and industry resources of **our shareholders**



- Strategically identify and select targets with proven or highly potential clinical benefits
- Leveraged our research hubs in **Shanghai** and **San Francisco** to develop **majority of** drug candidates in-house, especially focusing on **differentiated bi/tri-specific** Abs innovative drug discovery technologies



- **Research hubs in Shanghai and San Francisco**

- At their prior positions in China, our **core clinical team members** played key roles in the submission of more than **60 IND applications, 22 NDAs** and the **successful approvals and launches of 16 products**
- Strategically design clinical trials and select optimal regulatory pathways toward commercialization in China with **maximum efficiency** and speed



Commercialization-ready Manufacturing Capabilities

Yuxi, Yunnan Phase 3 and Future Commercial Manufacturing Site



Cutting-edge Continuous-flow Manufacturing Technologies

- With quality excellence and enhanced cost efficiencies, boasting state-of-the-art **concentrated fed-batch (CFB)** and **perfusion** technologies that allow us to generate **higher titer and yield with smaller bioreactors** than the conventional technologies, driving the high-end of the industry range (lower CapEx, OpEx and COGm)
- Designed to operate under GMP requirements, inherited from ~15yrs of Walvax commercial vaccine production



Bioreactors: 3 x 200L, 4 x 500L (~8,000 m² Floor Space)

- Supporting both pivotal trials and product launch (regulatory advantage), and avoid CMC Post-approval Manufacturing Changes
- Supporting our commercial manufacturing needs in the near future for, including but not limited to, our first three products (GB226, GB242 and GB22).

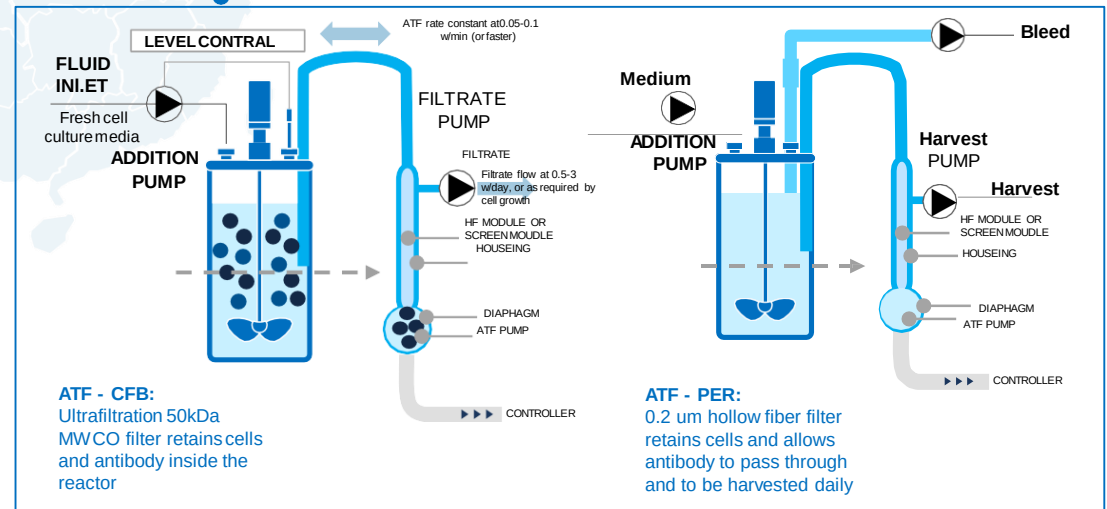


Yuxi,
Yunnan

Shanghai R&D Center with Pilot Plant for IND and Clinical Supplies

- Strong late-stage CMC capabilities with approximately one decade of technology precipitations since 2007. 20+ IND applications and most phase 1/2 clinical trials supported
- Process development: ATF-CFB and ATF-PER **continuous-flow cell culture technology development for higher titer and yield**; Antibody purification platform for DSP PD
- Quality: state-of-art, GMP-designed analytical and quality control platform for extensive product characterization, comparability study, QC method development and qualification, and product releases; QMS system designed to be compliant with GMP operations and NMPA, FDA, and ICH guidelines
- **New facility with over 43,000 sqm** to be built in Lin-Gang Special Area

Shanghai





Establish Genor commercialization foundation and GB226 launch readiness by 1H21

Our mission		- To launch new product successfully in short-middle term - To be a leading commercial organization in long term in China and Asia
Our strategies		- Drive comprehensive commercial capability and productivity to excel over competitors - Maximize brand differentiation by focusing disease focus, partnership and innovation
GB226 launch readiness	Organization, people & training	- Lean and high productive structure and organization setting 90% budgeted HCs have been hired and on-board by end of July - All of commercial members trained as being knowledgeable on disease, Onco-immunology and product and selling skill.
	Process, System & Data	All of critical working processes reviewed and systems established e.g. CRM, DDI, SAP-SD and OA optimizing etc. Customer data consolidated and internal user function set up
	Brand strategic plan	- Brand strategy overall is well prepared with continuously refining detail plan and projects. - Target customers have been outlined and selected with moving to visit and promote for appropriate corporate and brand message delivery. - HE study has been closed with useful outcome supporting to brand pricing and access strategy.
	Partnership & collaboration	- CSO partner was selected and co-promotion plan is well preparing by both parties 3PL, major distributors, DTP pharmacies, data and digital partners and NGO(PAP) have been validated and contracted in most
	Market warming up	- Covered over 70% doctors in lymphoma by daily bases as well as other Oncologist e.g. GYN - Participate seven national or regional hematology or lymphoma conferences with GB226 PTCL study data presentation covering over 3,000 doctors offline and online e.g. The First National Conference Lymphocytic Disease of the Chinese Medical Association



Innovative Commercial Model to Maximize Market Opportunity

(Build up in-house capable commercial team with CSO co-promotion, a hybrid sales model, to support the launch of late-stage candidates including GB226)

- Our in-house commercial team is fully setup and well trained for the upcoming new product launch of GB226
- Covers core lymphoma market and other defined segments while launch GB226, and will continue to expand sales force with GB226 NRDL entry in 2022 and other new indication approval in the future
- Solidly formed partnership with CSO for non-core market promotion, 3rd party logistic and distributor companies
- Started pre-launch marketing activities e.g. participated multiple national and regional hematology and lymphoma conferences to share strong data of GB226 r/r PTCL study

In-house sales and CSO joint effort for GB226 launch

Target to cover 80-90% PD1/L1 market by hybrid sales model

Commercial functions	Core market	Non core market
Sales	Genor in-house team	CSO
Marketing/medical	Genor team	CSO collaborates for activity
Supply/channel	Genor team	
Access strategy	Genor team e.g. NRDL, pricing	
Access execution	Genor team	CSO
CRM/data/training	Genor team	



* NRDL national reimbursement drug list in China



Seasoned Management Team with Proven Track Records



Dr. Feng GUO

Chief Executive Officer, CEO



Dr. Jack HU

Chief Strategy Officer, CFO



Dr. Shuhua HAN

Chief Scientific Officer, CSO



Dr. Joe ZHOU

President Executive Officer



Ms. Tong LI

Chief Medical Officer, CMO



Mr. Wende CHEN

Chief Operation Officer, COO



Dr. Steven KAN

Chief Technology Officer, CTO



Mr. Mark F. KUBIK

Chief Business Officer, CBO



Ms. Yao CHEN

Head of Regulatory Affairs





Upcoming Events

GENOR
BIOPHARMA



Upcoming Milestones

Key Events	Timing
GB261 (CD20/CD3) – First Patient Enrollment in Australia	3Q21
GB226 (PD-1) – NDA approval for r/r PTCL	2H21
GB226 (PD-1) – Commercial Launch with 1st indication of r/r PTCL	2H21
GB491 (CDK4/6) – First Patient Enrollment for Phase 3 trial for 1L HR+/HER2- mBC	4Q21
GB491 (CDK4/6) – First Patient Enrollment for Phase 3 trial for 2L HR+/HER2- mBC	4Q21
GB492 (STING) – First Patient Enrollment for solid tumor	4Q21
GB261 (CD20/CD3) – IND Filing in China and the US	4Q21
GB263T (EGFR/c-Met/c-Met) – GLP Tox Study Initiation	4Q21
GB263T(EGFR/c-Met/c-Met) – AUS FIH CTA Submission	1H22
GB263T (EGFR/c-Met/c-Met) – IND Filing in China and the US	1H22
GB242 (TNF- α) – NDA approval	1H22
GB261 (CD20/CD3) – Initial POC Data	1H22
GB263T (EGFR/c-Met/c-Met) – Initial POC Data	2H22
GB491 (CDK4/6) – Interim Data for 2L HR+/HER2- mBC	2Q23



Financial Overview

GENOR
BIOPHARMA



Financial Overview – Income Statement

RMB' mn	Six Months Ended 30 June	
	2021	2020
Revenue	-	3.8
Cost of revenue	-	(0.8)
Gross Profit	-	2.9
Selling expenses	(27.1)	-
Administration expenses	(117.4)	(93.7)
Research and Development expenses	(271.5)	(347.8)
Other income	5.6	2.0
Other gains/(losses)-net	16.2	(92.3)
Operating loss	(394.2)	(528.8)
Finance Income	7.4	0.6
Finance Costs	(19.7)	(9.1)
Finance costs-net	(12.3)	(8.4)
Loss before income tax	(406.5)	(537.3)
Income tax credit	4.0	2.7
Loss for the year	(402.5)	(534.6)

Expenses

- R&D expenses decreased, mainly due to the decrease of employee benefit expenses
- The increase in Administration Expenses was due to i) the increases of employee benefit expenses for managerial personnel and (ii) increases of head counts.
- The selling expenses was due to the set up of commercial team.

Net loss for the year

- Net loss for the year was RMB 402.5mn

* All numbers are rounded to one decimal place



Financial Overview – Balance Sheet

RMB' mn	Jun-21	Dec-20
Cash and cash equivalents	2,579.1	2,929.7
Restricted bank deposits	2.0	2.0
Inventories	43.7	31.5
Contract cost	1.8	1.8
Other receivables, deposits and prepayments	85.1	108.7
Amounts due from related parties	27.8	27.8
Total Current Assets	2,739.5	3,101.4
Property, plant and equipment	191.7	200.3
Right-of-use assets	26.0	28.9
Intangible assets	171.3	156.9
Other receivables, deposits and prepayments	136.4	80.3
Deferred income tax assets	9.2	5.6
Total Non-Current Assets	534.6	472.0
Total Assets	3,274.1	3,573.4
Trade payables	92.2	91.7
Contract liabilities	5.6	4.9
Other payables and accruals	132.4	116.3
Lease liabilities	14.9	15.0
Amounts due to related parties	12.3	17.0
Provision	1.5	0.0
Deferred income	3.7	3.7
Total Current Liabilities	262.7	248.7
Contract liabilities	0.0	0.8
Lease liabilities	17.4	16.0
Amounts due to related parties	32.7	34.8
Deferred income	20.9	21.9
Deferred income tax liabilities	13.7	14.1
Total Non-Current Liabilities	84.7	87.6
Total Liabilities	347.4	336.3
Total Equities	2,926.7	3,237.1



Cash Balance

- As of June 30, 2021, our total cash and cash equivalents were Rmb 2,579m.

* All numbers are rounded to one decimal place



Q&A

GENOR
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