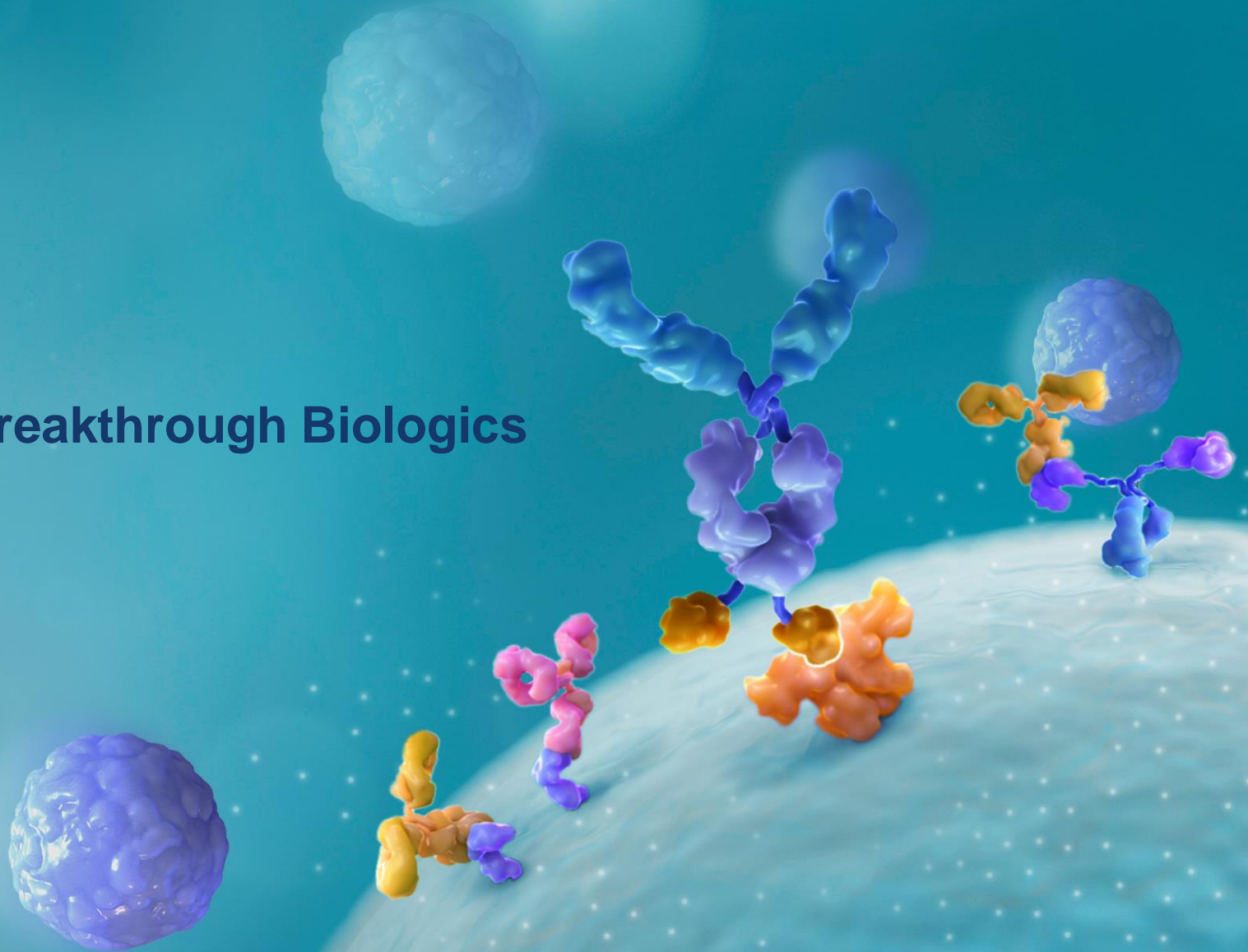


GI Innovation

Innovative Healthcare with Breakthrough Biologics

Company Introduction, September 2024



Forward Looking Statements

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Key milestones achieved



2017~2021

- Jul 2017 Founded
- May 2018 Strategic Partnership with **Samsung Biologics**
- Nov 2019 L/O GI-101 to Simcere, China for \$ 790M in Greater China Region
- Jul 2020 L/O GI-301 to Yuhan, Korea for \$ 1.2B Excluding Japan (Sublicensing, 50/50 Profit Sharing)
- Jul 2020 Collaboration with MSD for GI101·Keytruda®
- Jun 2021 GI-101 Ph I/II IND (US, KR)
- Jul 2021 GI-301 Ph I IND (KR)

2022~2023

- May 2022 GI-101 Ph I/II Granted \$ 5.8M from Korea Drug Development Fund (KDDF)
- Sep 2022 GI-108 Granted \$ 1.7M from KDDF
- Oct 2022 GI-101 Orphan Drug Designation for MCC (US FDA)
- Feb 2023 GI-102 Ph I/II IND (US/KR)
- Mar 2023 **IPO on the KOSDAQ**
- Oct 2023 L/O GI-301 to Maruho, Japan for \$221M in Japan

2024~

- Jun 2024 GI-102 Orphan Drug Designation for sarcoma (US FDA)
- Aug 2024 Collaboration with MSD for GI102·Keytruda®
- Nov 2024 GI-102 Ph II Granted \$ 5.8M from Korea Drug Development Fund (KDDF)
- Nov 2024 GI-128 Granted \$ 0.67M from KDDF

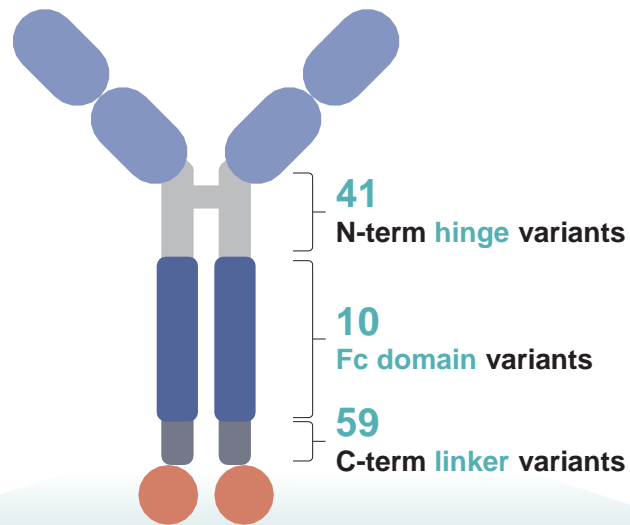
*Partial support from KDDF

Integrated GI-SMART™ platform for the accelerated screening of bispecific proteins

Expedited identification of optimal candidate molecules through high-throughput screening system

SMART-Selex™

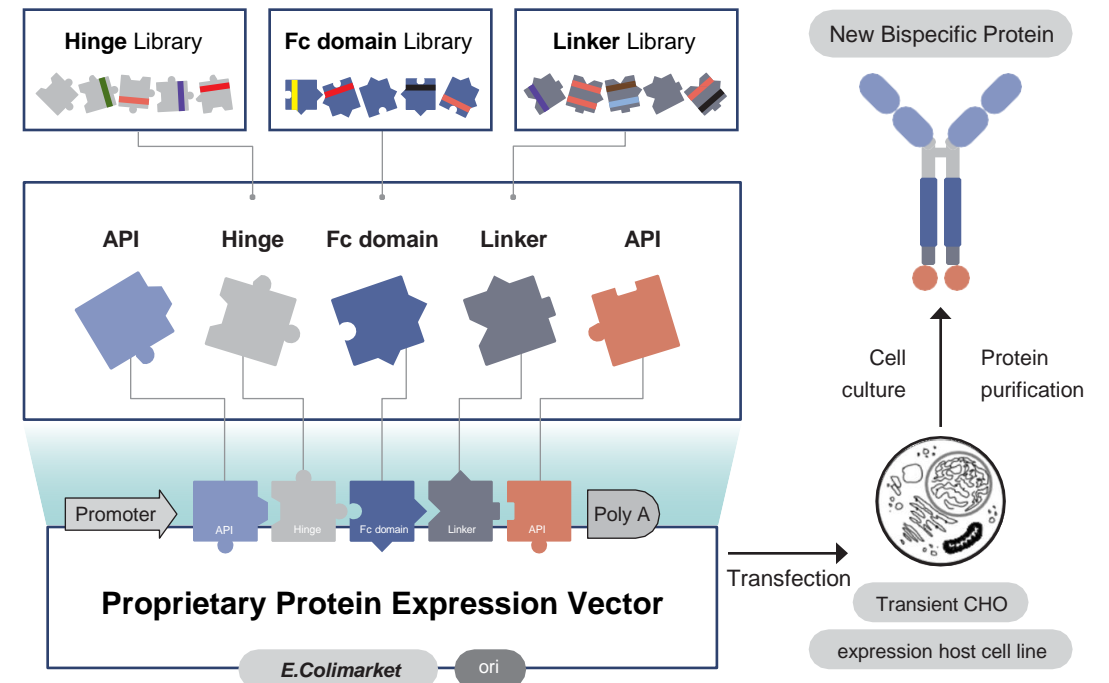
Libraries for specific of bispecific proteins
Enable quick assembly of stable and functional proteins



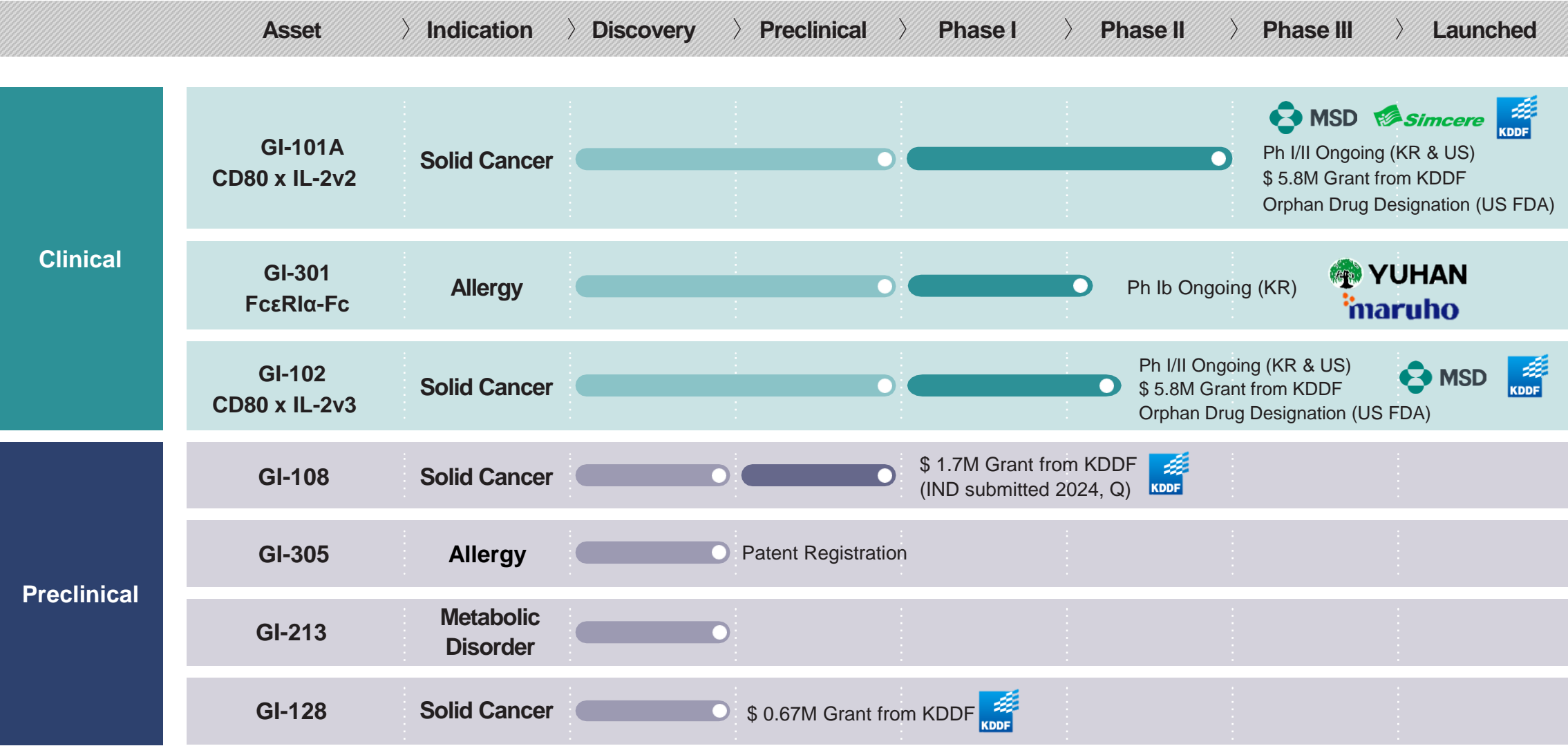
$$41 \times 10 \times 59 = 24,190 \text{ variants}$$

SMART-cLego™

Fast cloning by Lego-like block integration into an
Expression vector to save cost and time of protein production



Pipeline





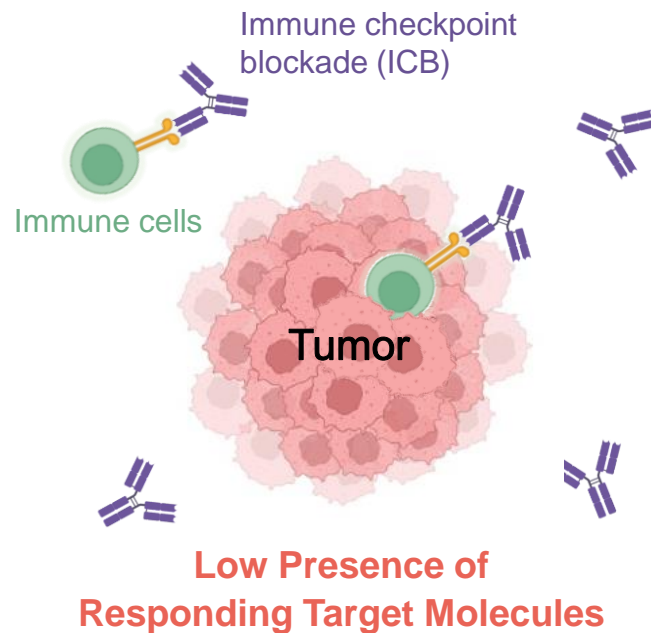
INVESTOR RELATIONS 2024

Immunocytokine 'GI-101A & GI-102'

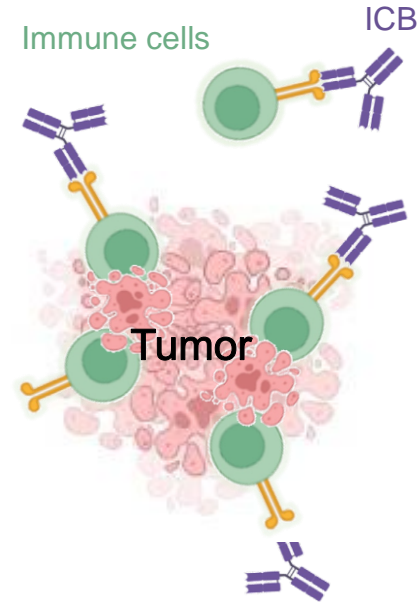


Immune cell is essential for immunotherapy

Insufficient Immune Cells Leads to Ineffective Treatment



Immunotherapy is Less Effective

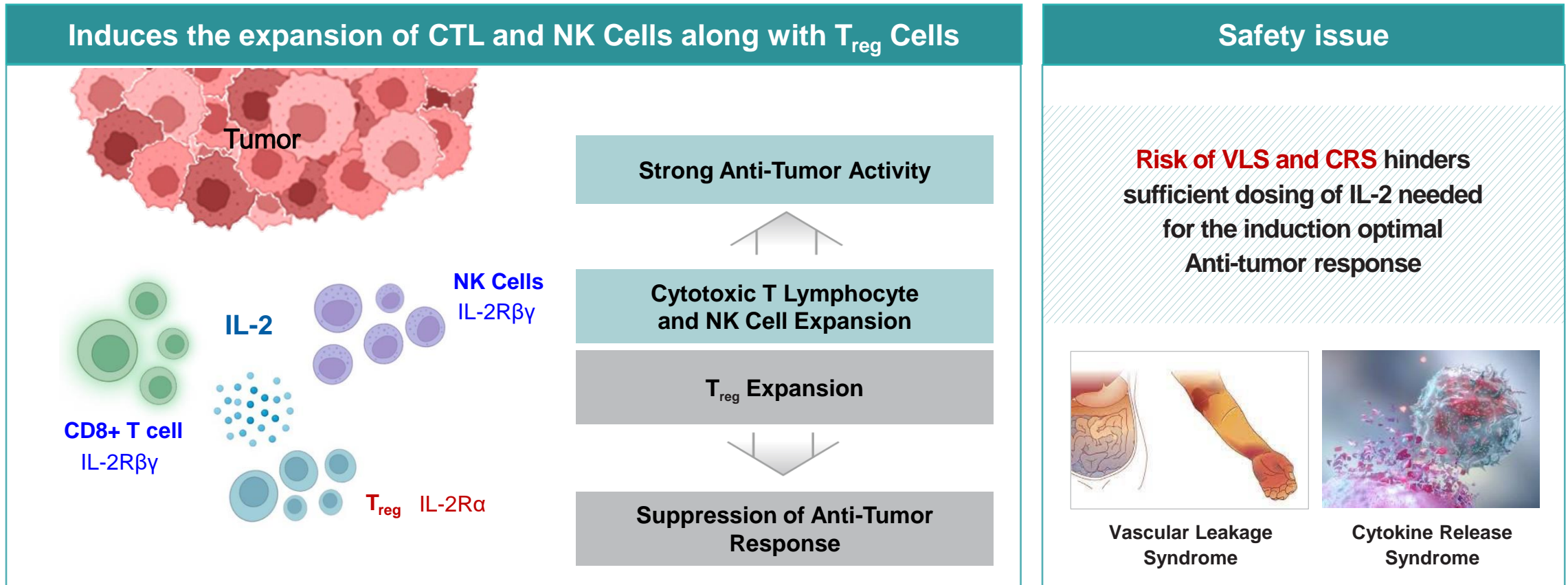


Immunotherapy is More Effective

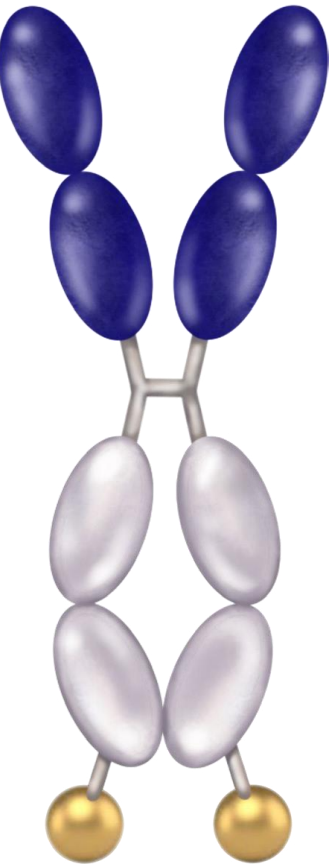
IL-2 increases the number and activity of the immune cells

Source: Dielhl et al., Oncotarget, 2017

IL-2 is a validated target, but its clinical use is limited



CD80/IL2v is a targeted cytokine: CD80 fused to an IL-2 variant



- Immune cell/tumor targeting
- Inhibits CD80/CTLA-4 interaction, thereby inhibiting Treg function
- Retains CD80 expression on APCs

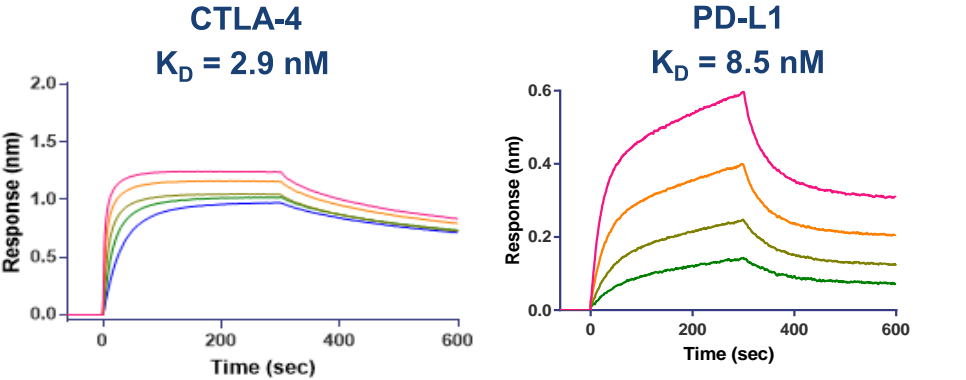


- Low FcγR/C1q affinity
- No antibody or C-dependent cytotoxicity



- GI-101: 2 amino acid substitution, IL-2Rα affinity reduced
- GI-102: 3 amino acid substitution, IL-2Rα affinity abolished
- Sustained binding to IL-2βγ receptors compared to wild type IL-2

Binding Affinity to CTLA-4 and PD-L1

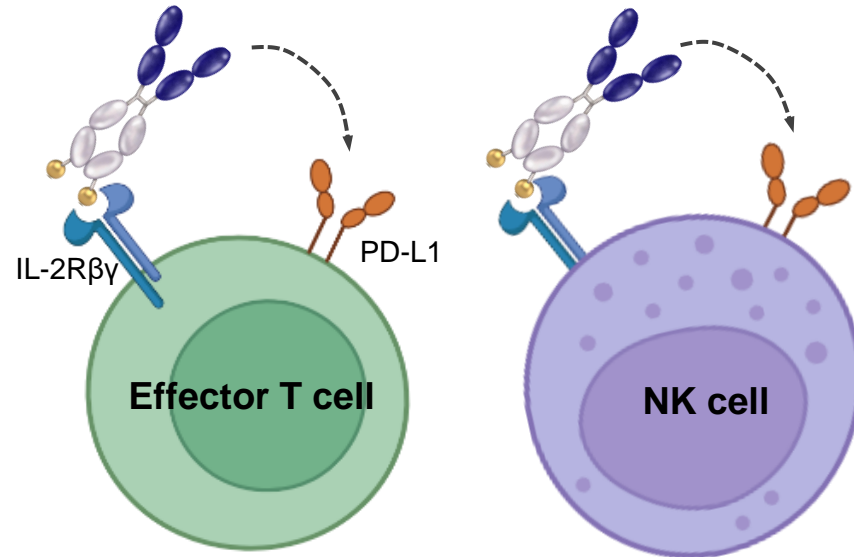


Binding Affinity to IL-2 Receptor (KD, nM)

Receptor	Proleukin® (IL-2 wild type)	NKTR-214 (2-PEG-IL2)	GI-101 (CD80 x IL-2v2)	GI-102 (CD80 x IL-2v3)
IL-2Rα	49.6 (x42)	486.6 (x8)	1830 (x1.3)	No binding
IL-2Rβ	2080	3951.8	1360	1340
IL-2Rαβγ	0.003*	-	0.006	0.127
IL-2Rβγ	0.102*	-	0.11	0.095
IL-2Rβγ/ IL-2Rαβγ	34	-	18.3	0.75

CD80/IL2v targets CD8+T and NK cells, while blocking Tregs

Effective CD8+T and NK cell targeting via cis-binding

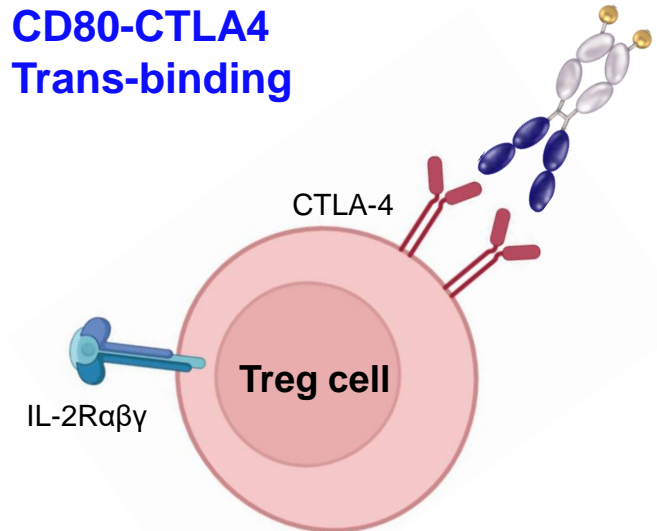


Cis-binding to IL-2Rβγ and PD-L1

- 1 Enables **avid and rigid binding of IL-2** on immune cells for strong proliferation and activation
- 2 Inhibits immune cell senescence

Directly inhibits Treg function

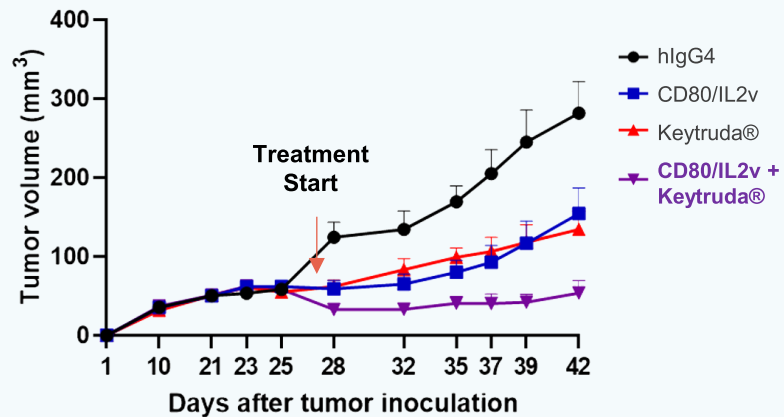
CD80-CTLA4 Trans-binding



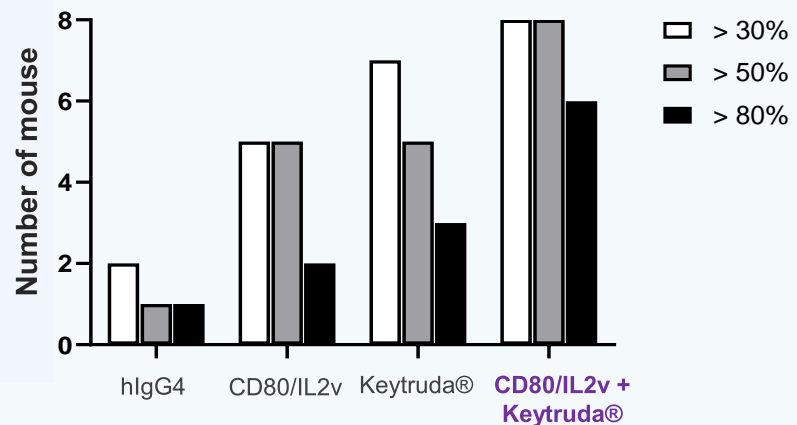
CD80/IL2v has synergistic anti-tumor efficacy in humanized mice

Tumor Volume

Humanized mouse model (MHC class I-null B2M NSG) implanting human PBMC transplantation, grafted with **MDA-MB-231, triple-negative breast cancer cell line**

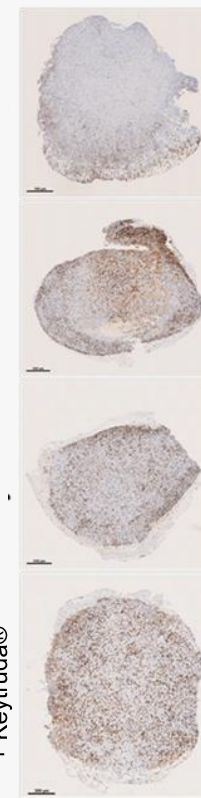
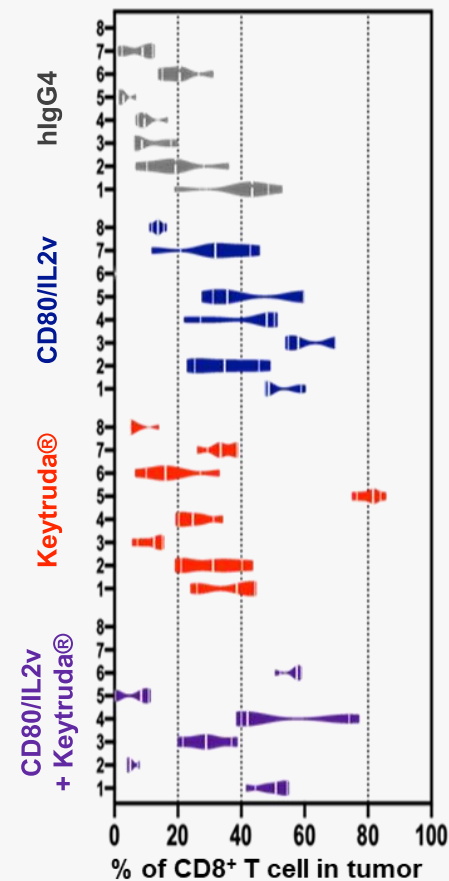


Tumor Growth Inhibition



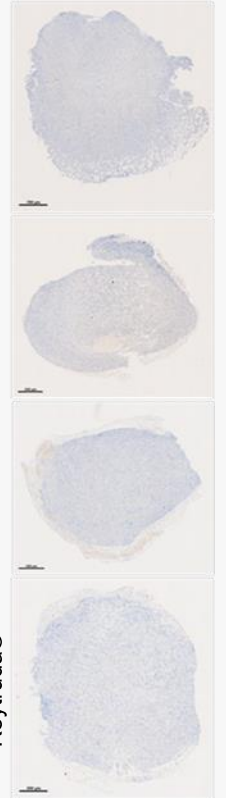
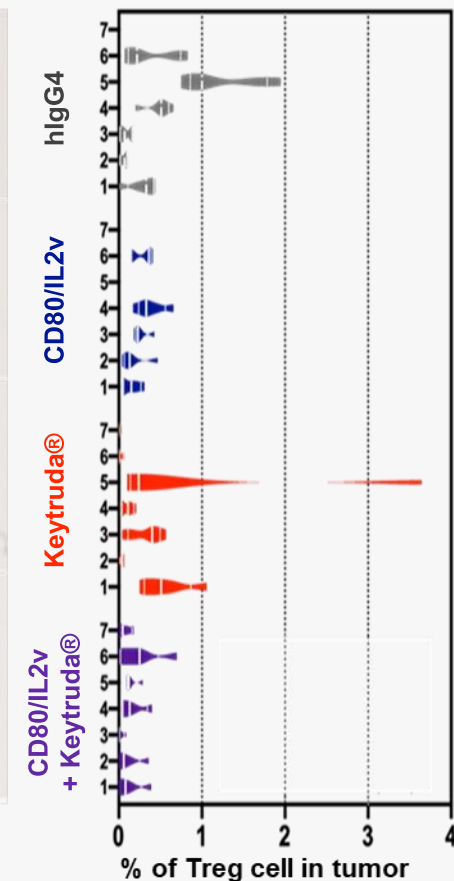
CD8+ T cells

CD80/IL2v significantly **increased tumor-infiltrating lymphocytes** (CD8+ T cell)

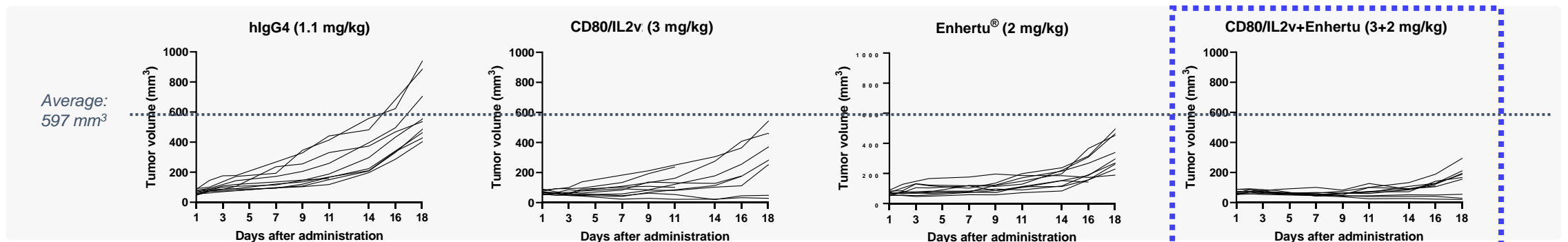
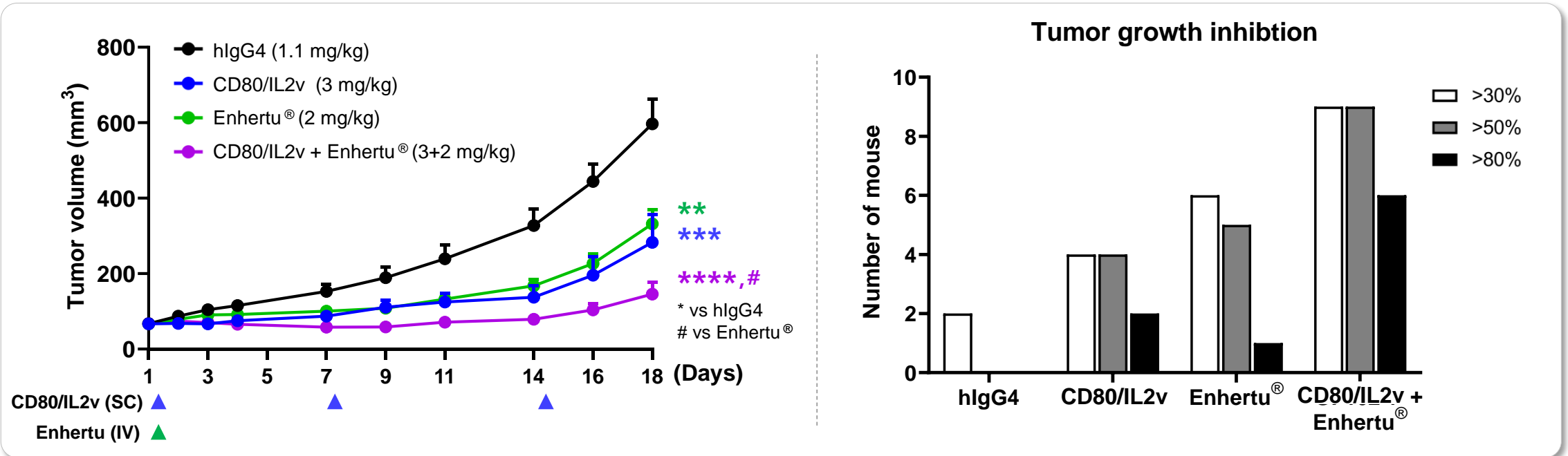


Treg cell

CD80/IL2v decreased the **density of immune suppressive Treg cells** within the tumor tissue



CD80/IL2v potentiates ADC efficacy in a murine breast cancer model



One-way ANOVA, Dunnett's test, # $p < 0.5$, * $p < 0.1$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$

CD80/IL2v is superior to competitors: reversing Treg suppression is key

	GI-101A/GI-102 ¹⁾	RG6279 ²⁾	SAR444245 ³⁾	IBI363 ⁴⁾	AB248 ⁵⁾
CD8+ T & NK Cell Proliferation					
Treg Suppression					
Localization to TME, dLN and spleen					
Improved PK Profile			Unknown		Unknown
Synergy with Other Treatment Modalities			Unknown		Unknown

1) GI Innovation presentation, Lee et al., ASCO 2024, 2) Bai et al., ASCO 2024, 3) Buchbinder et al., AACR 2023, 4) Bai et al., ASCO 2024,, 5) Buchbinder et al., AACR 202



INVESTOR RELATIONS 2024

GI-101A Clinical results



cPR in pancreatic adenocarcinoma with liver metastasis

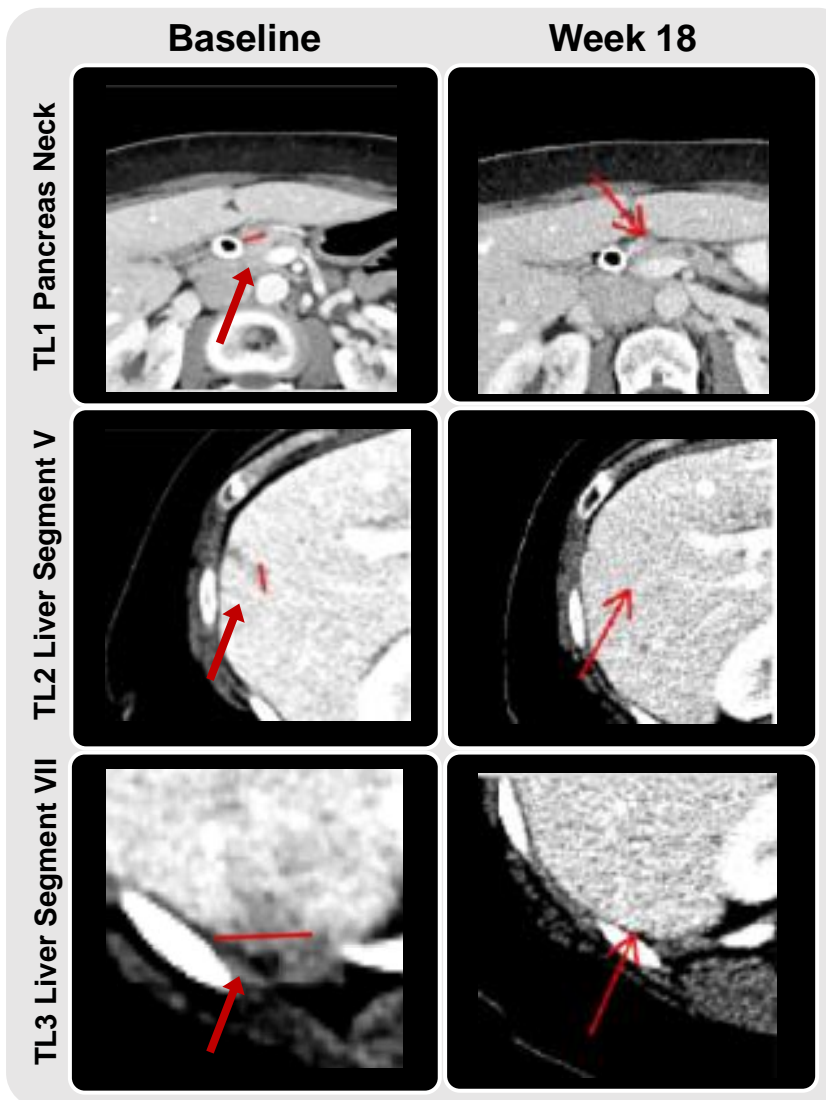


71 years old female
Pancreatic adenocarcinoma
First diagnosis: 20 Jul 2023
MSS in liquid biopsy
Target lesion: Pancreas, liver

GI-101A 0.05 mg/kg + Pembrolizumab
Treatment duration: 184 days+
Cycle 7 ongoing

Treatment history

1L	FU Oxaliplatin Irinotecan	DoT : 71 days BoR: PD
2L	Gemcitabine Abraxane	DoT : 56 days BoR: PD



Week 6:
-72.7% Reduction
Partial Response (PR)

Week 12:
-72.7% Reduction
Confirmed PR

Week 18:
-86.3% Reduction
Confirmed PR

Duration of response 86 days+



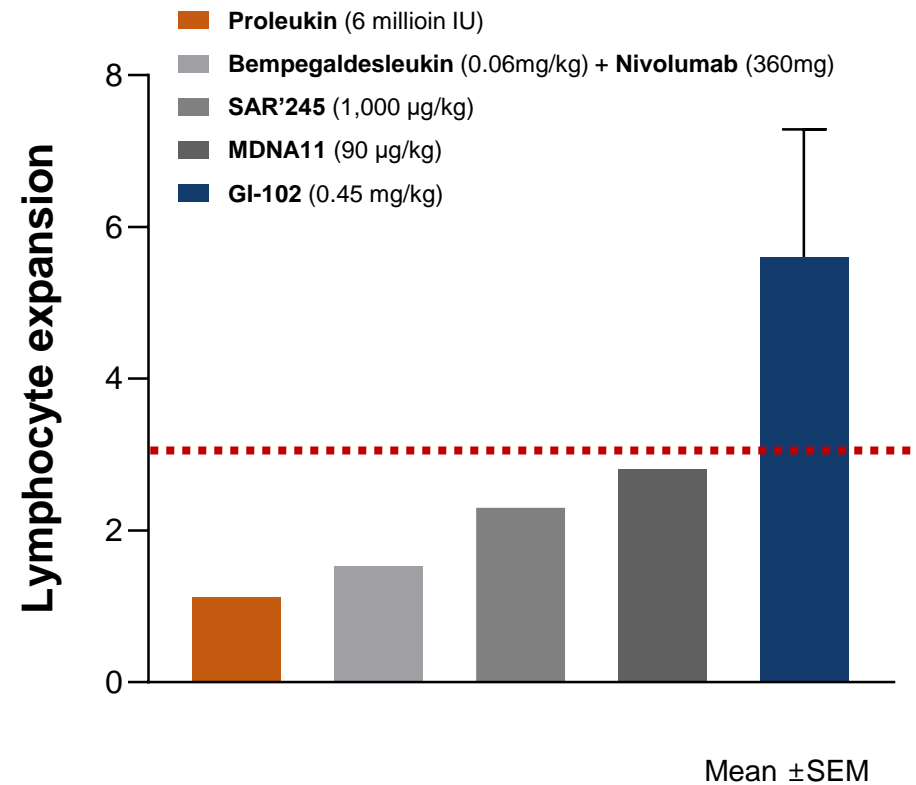
INVESTOR RELATIONS 2024

GI-102 Clinical results

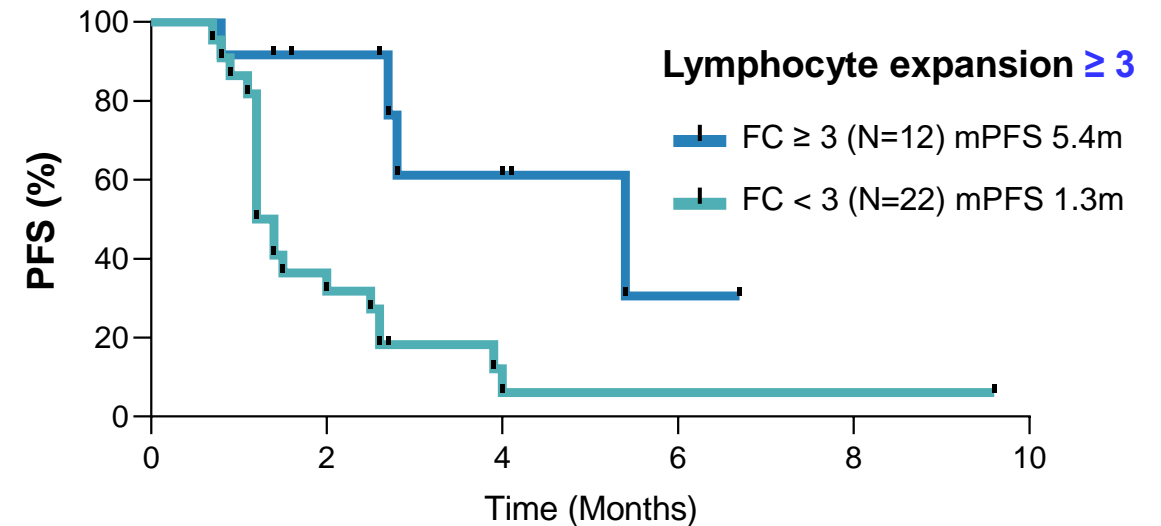


GI-102 induced significant expansion of lymphocytes in human

Lymphocyte expansion after IL-2 treatment



GI-102



1) Lissoni P, Oncology, 1994; 2) Diab et al. J Clin Oncol 2023;
3) Sanofi R&D Day 2020; 4) Q3 2023 Medicenna Corporate Overview

GI-102 has demonstrated great safety and tolerability up to 0.45 mg/kg

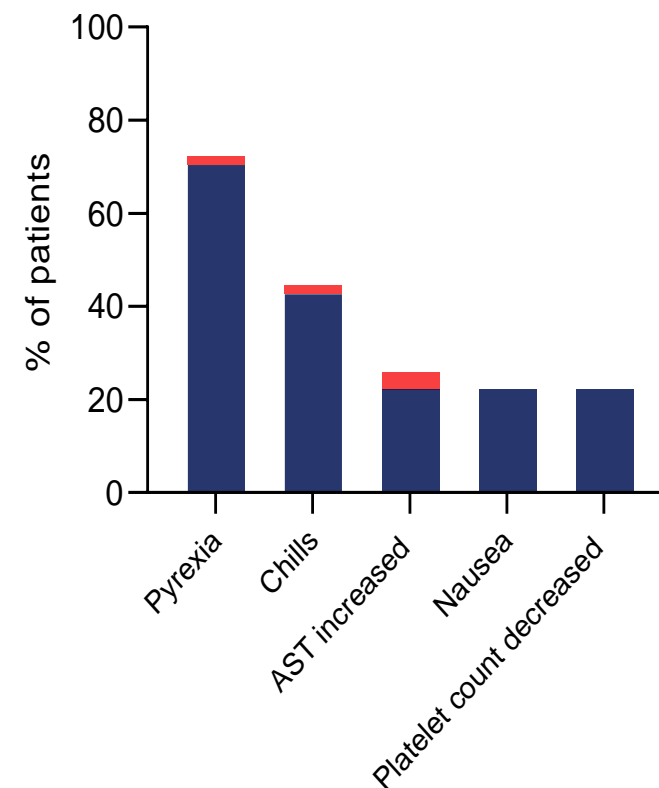
In dose escalation part (0.06-0.45 mg/kg), **no DLTs have been observed**

# of subjects (%)	GI-102 (N=35)	Proleukin® (N=270, historical data)
Patients with TEAEs		
≥ Grade 3 TEAE	22 (40.7%)	257 (95.0%) [†]
≥ Grade 4 TEAE	6 (11.1%)	94 (35.0%) [†]
AE leading to death	0 (0%)	6 (2.0%)[†] Hypotension, vomiting, diarrhea, bilirubinemia, oliguria, fever/chill, thrombocytopenia, SGOT increased, creatinine increased, malaise, rash, dyspnea, confusion, anemia, nausea, leukopenia
Common TRAEs (>20%)	Pyrexia, chills, nausea, AST increased	

- All Grade 4 TRAEs were transient lymphopenia, thought to be related to lymphocyte migration to lymphoid organs

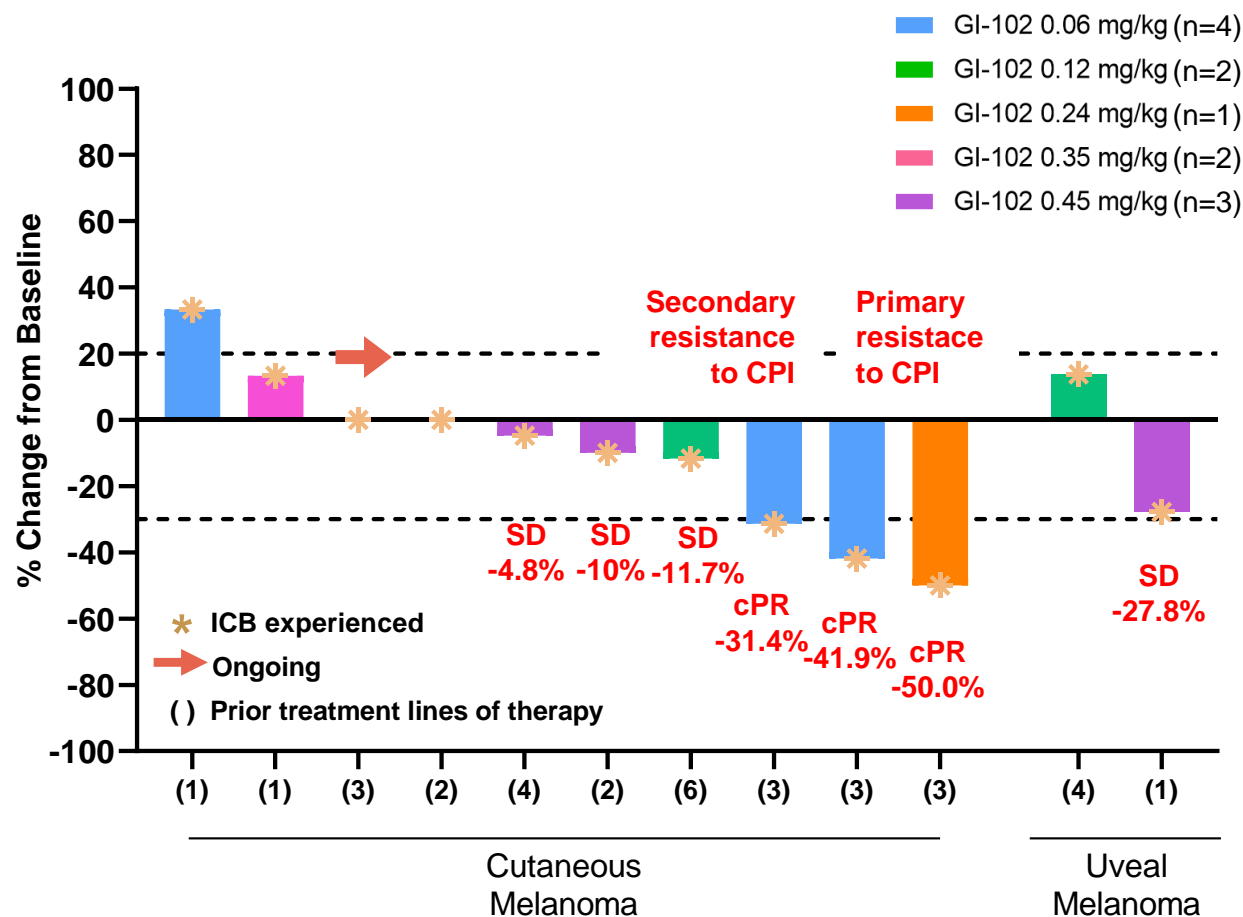
[†] Proleukin® Medical Reviewers Report BLA Supplement 97-0501; Not a head-to-head comparison

>20% TRAEs



GI-102 shows strong monotherapy activity

Metastatic, heavily pretreated melanoma (N=12)



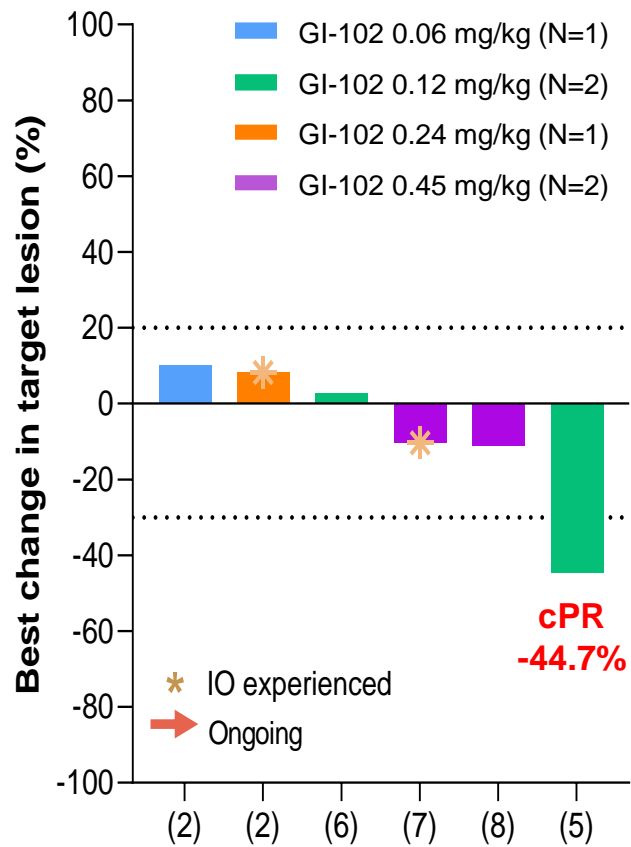
Clinical results in CPI refractory metastatic melanoma

Treatment regimen	Response rate (Responder/Total)
Pembrolizumab + lenvatinib (LEAP-004; MSD) ¹⁾	21.4% (22/103)
Nivolumab + relatlimab, 1 prior CPI therapy (RELATIVITY-020; BMS) ²⁾	12.0% (42/351)
Nivolumab + relatlimab, ≥ 1 prior CPI therapy (RELATIVITY-020; BMS) ²⁾	9.2% (15/163)
Nemvaleukin (Alkermes) ³⁾	9.1% (4/44)
SAR444245 (Sanofi) ⁴⁾	0% (0/12)
Bempegaldesleukin (Nektar; BMS) ⁵⁾	0% (0/7)
GI-102 (GI Innovation)	30% (3/10)

1) Arence et al., J Clin Oncol 2023; 2) Ascierto et al., J Clin Oncol 2023; 3) ASCO 2022 Abstract 2500; 4) ESMO 2022 747P; 5) Bentebibel et al., Cancer Discov 2019

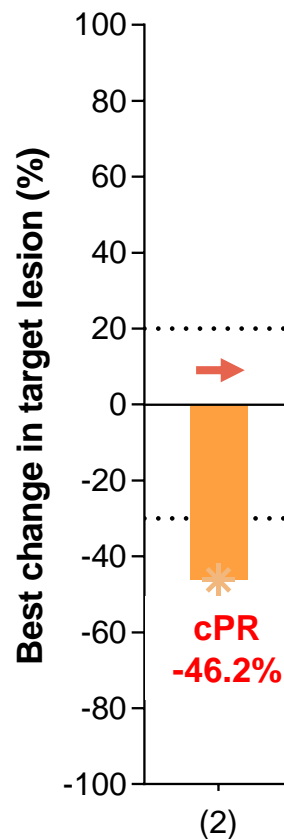
Objective responses in diverse indications

Ovarian cancer (N=6)

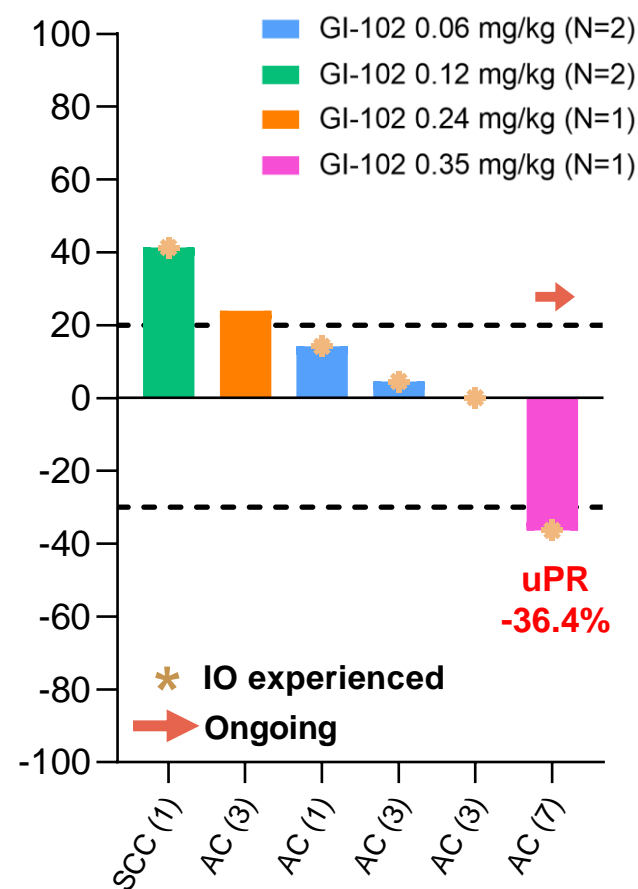


() Prior treatment lines of therapy

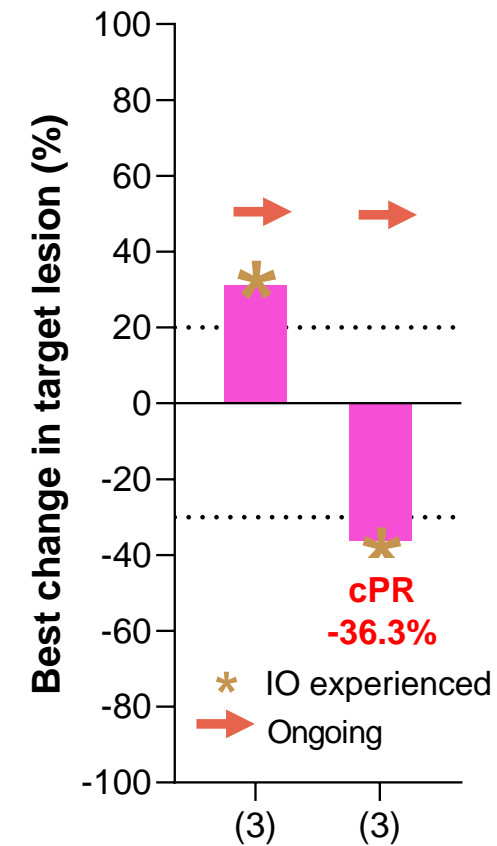
MCC (N=1)



NSCLC (N=6)



Bladder cancer (N=2)

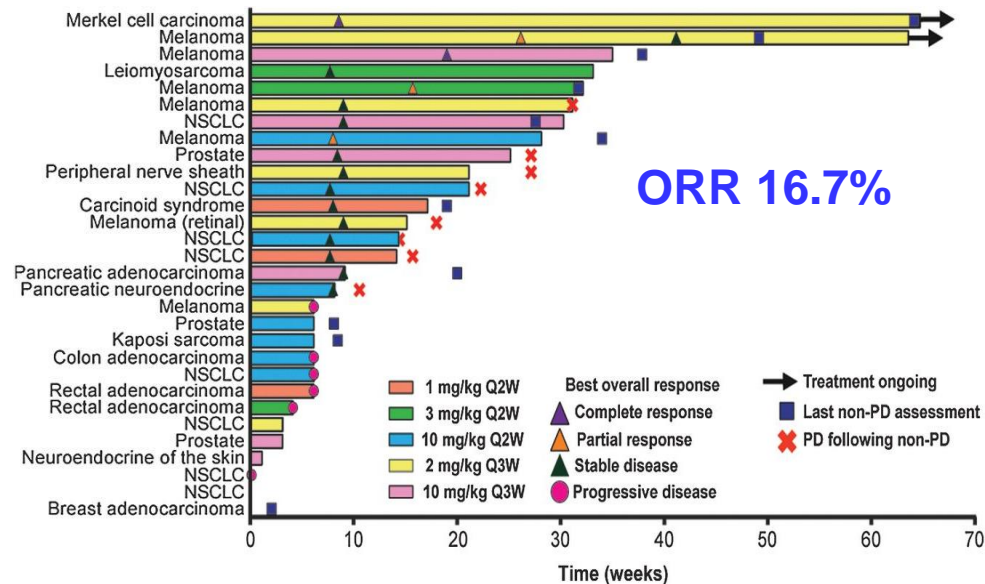


Historical early phase ORR results with immunotherapy agents

Pembrolizumab (Keytruda®, Merck)¹

Immune checkpoint blockade(ICB)-naïve

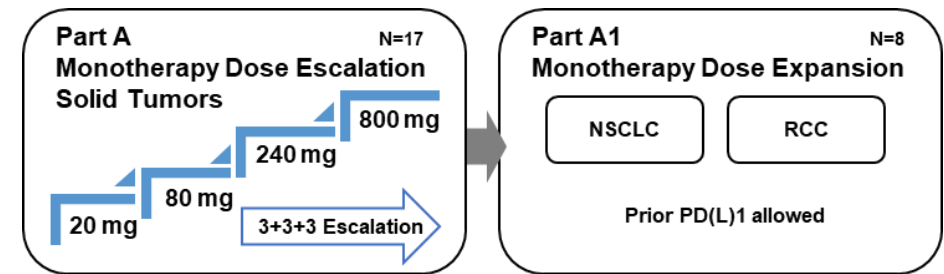
Phase 1, Advanced solid tumors, N=30



Relatlimab (Opdualag™, BMS)²⁻⁴

IO-experienced

Phase1/2a, Advanced or recurrent malignancies, N=25



ORR 4%

GI-102 is showing comparable ORR with pembrolizumab in IO-experienced setting

1) Amita et al., Clin Cancer Res., 2015; 2) Hussein et al., NEJM., 2022; 3) Opdualag Assessment report, 2022; 4) Georgina et al., NEJM, 2023



INVESTOR RELATIONS 2024

GI-102 for cell therapy



IL-2 can be combined with different treatment modalities for cancer

The first tumor-derived autologous T cell immunotherapy approved by FDA

FDA grants accelerated approval to lifileucel for unresectable or metastatic melanoma

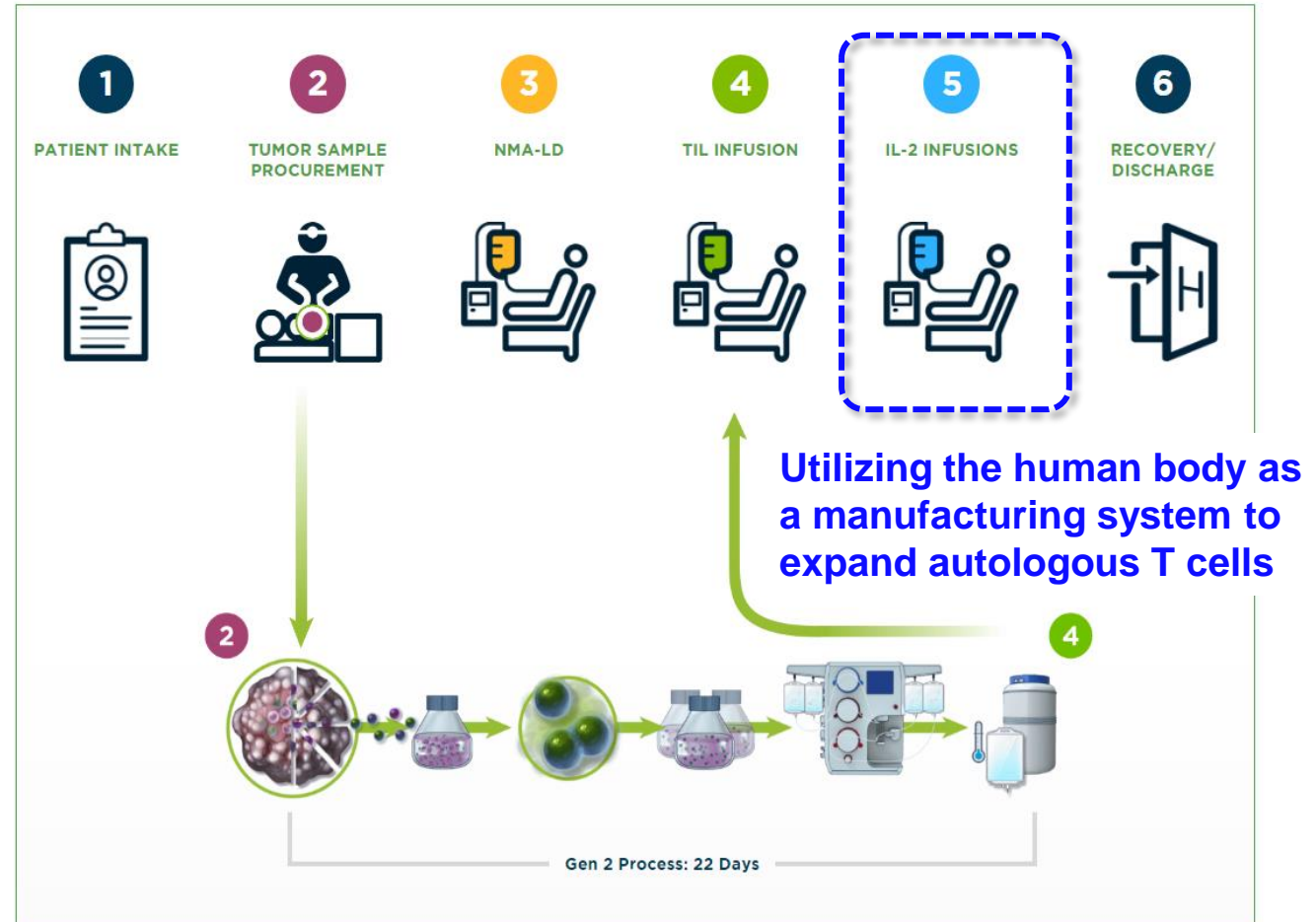
On February 16, 2024, the Food and Drug Administration granted accelerated approval to lifileucel (Amtagvi, Iovance Biotherapeutics, Inc.), a tumor-derived autologous T cell immunotherapy, for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor.

ORR 31.4%

Full prescribing information for Amtagvi will be posted [here \(/vaccines-blood-biologics/development-approval-process-cber/2024-biological-license-application-approvals\)](https://www.fda.gov/drugs/development-approval-process-cber/2024-biological-license-application-approvals).

Safety and efficacy were evaluated in a global, multicenter, multicohort, open-label, single-arm trial in patients with unresectable or metastatic melanoma who had previously been treated with at least one systemic therapy, including a PD-1 blocking antibody, and if BRAF V600 mutation-positive, a BRAF inhibitor with or without a MEK inhibitor. Among 89 patients who received lifileucel, two patients were excluded because the product did not meet specification and five patients were excluded due to product comparability. Lifileucel was administered following a lymphodepleting regimen consisting of cyclophosphamide 60 mg/kg daily with mesna for 2 days followed by fludarabine 25 mg/m² daily for 5 days. Three to 24 hours after infusion, patients received IL-2 (aldesleukin) at 600,000 IU/kg every 8 to 12 hours for up to 6 doses in order to support cell expansion in vivo. The median administered lifileucel dose was 21.1×10^9 viable cells. The median number of administered IL-2 (aldesleukin) doses was 6.

Streamlined 22-day GMP manufacturing process



Safety of lifileucel and Proleukin® is highly problematic

Grade 3/4 Hematologic Lab Abnormalities*

Preferred Term, n (%)	Grade 3/4
Leukopenia	156 (100.0)
Lymphopenia	156 (100.0)
Neutropenia	156 (100.0)
Thrombocytopenia	147 (94.2)
Anemia	111 (71.2)

Non-Hematologic TEAEs in ≥30% of Patients*†

Preferred Term, n (%)	Any Grade	Grade 3/4
Chills	117 (75.0)	8 (5.1)
Pyrexia	81 (51.9)	17 (10.9)
Febrile neutropenia	65 (41.7)	65 (41.7)
Hypophosphatemia	58 (37.2)	41 (26.3)
Hypotension	52 (33.3)	17 (10.9)
Fatigue	51 (32.7)	6 (3.8)
Diarrhea	48 (30.8)	2 (1.3)

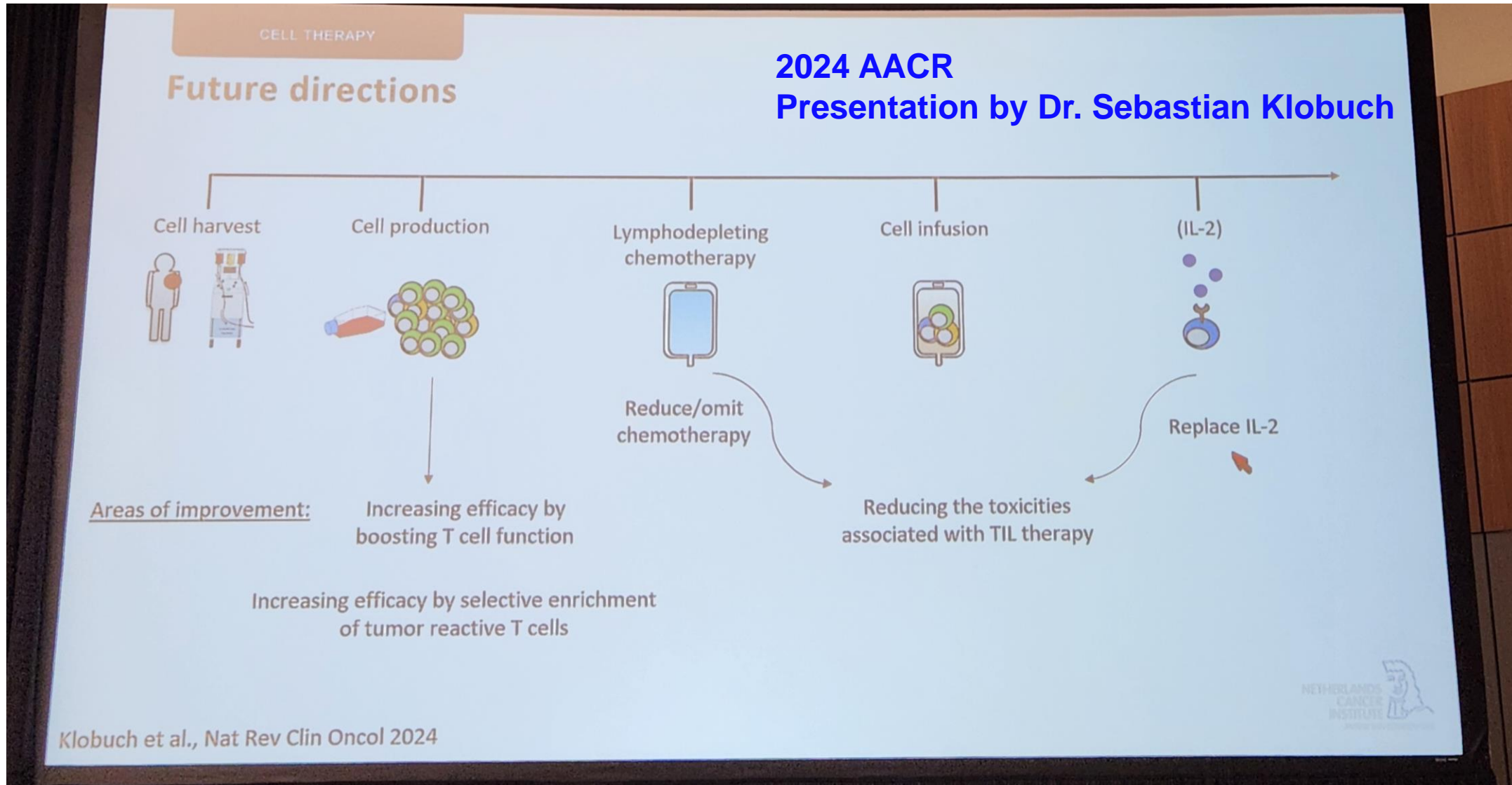
WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, CARDIOPULMONARY and RENAL IMPAIRMENT

See full prescribing information for complete boxed warning.

- Monitor patients for prolonged severe cytopenia and monitor for internal organ hemorrhage (5.1, 5.2, 5.3)
- Treat severe infections (5.1, 5.4)
- Monitor cardiopulmonary and renal functions throughout the treatment course (5.1, 5.5, 5.6, 5.7)

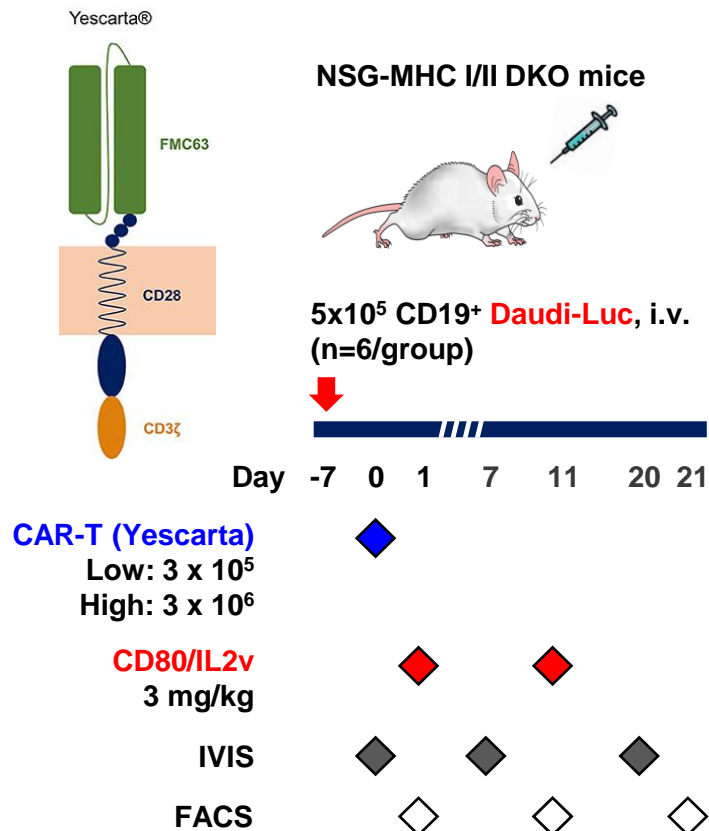
Administer in an inpatient hospital setting. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available (2.1, 6.1)

TILs and CAR-T for solid tumors require a safer IL-2 option



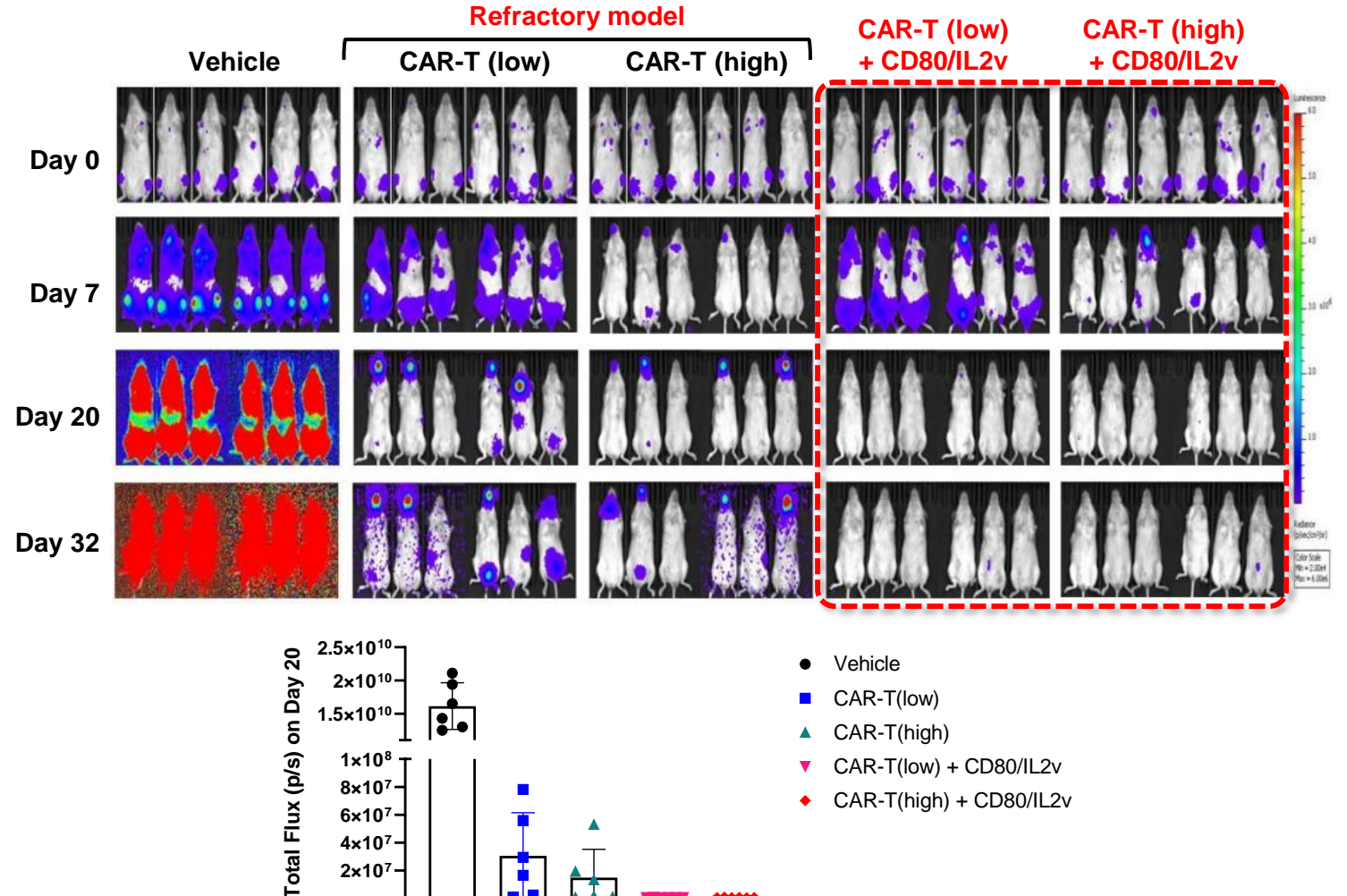
CD80/IL2v plus CAR-T therapy causes complete tumor rejection in mice

Experimental design

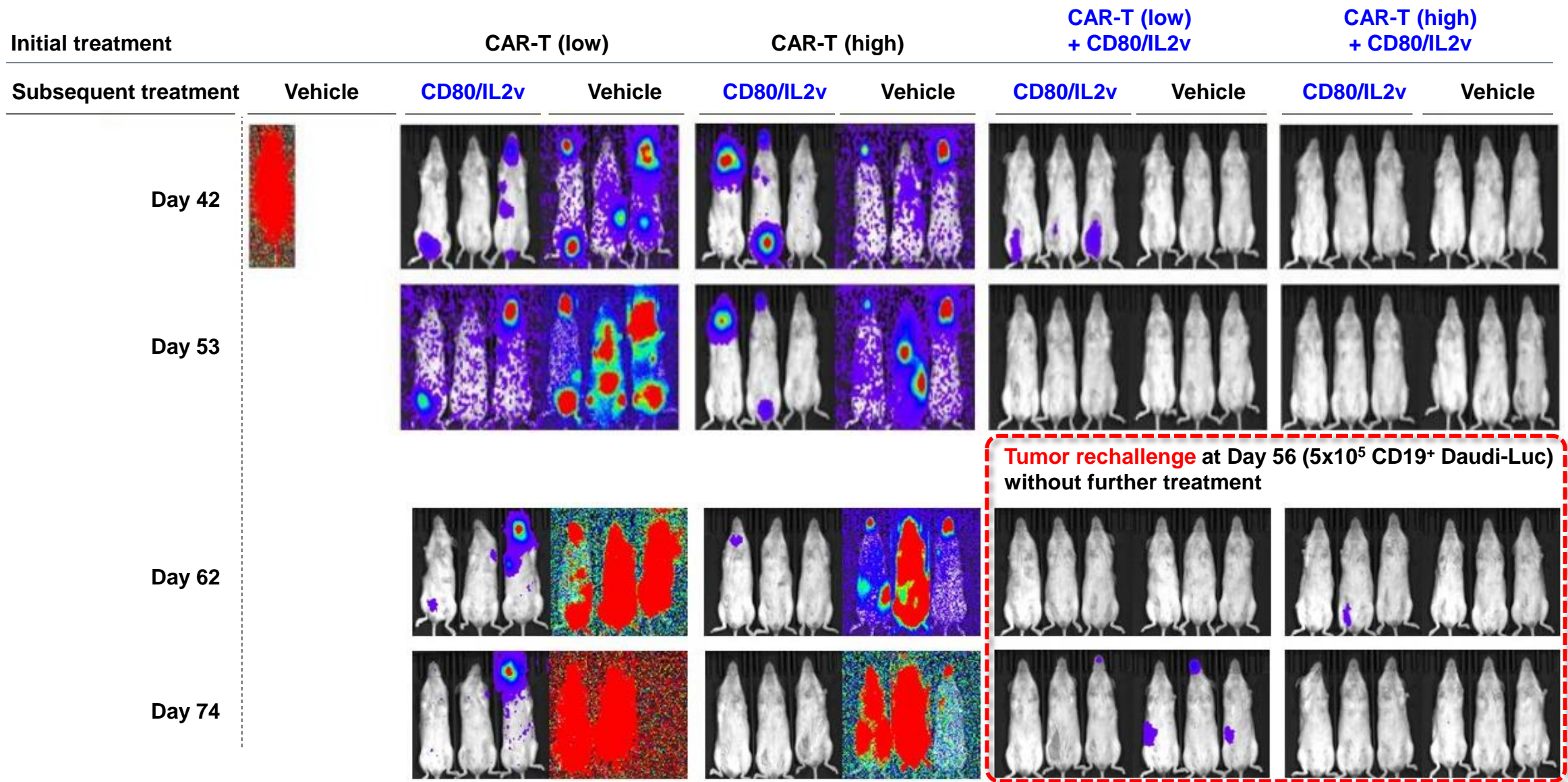


Ref: Cerrano et al., Front. Immunol., 2020

CD80/IL2v plus CAR-T shows enhanced anti-tumor activity vs CAR-T alone



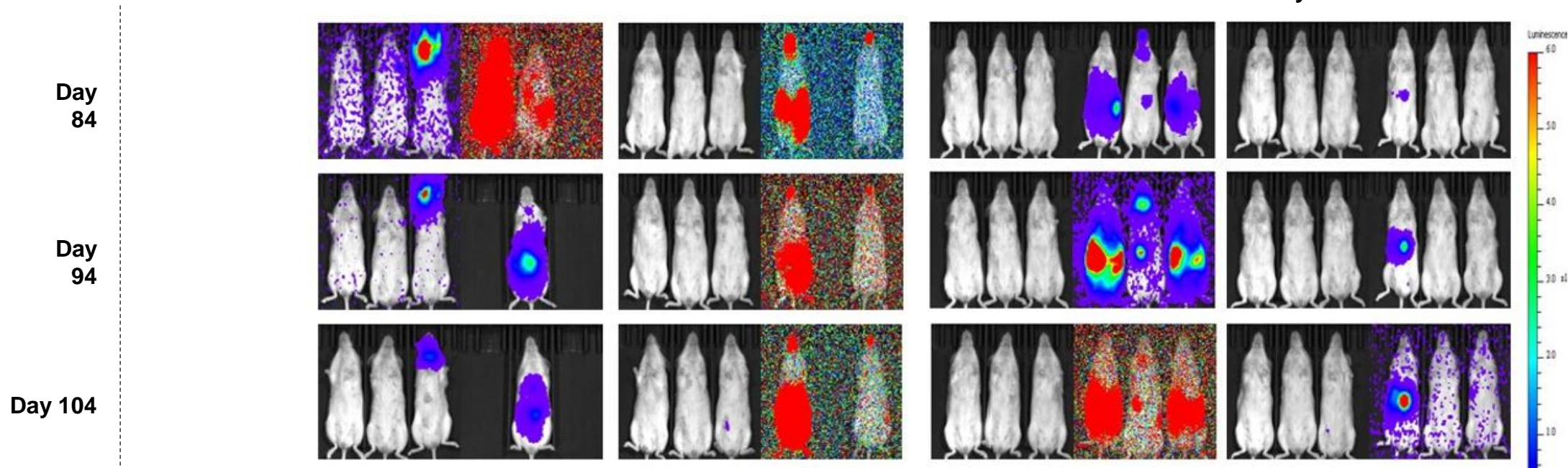
CD80/IL2v suppresses tumor recurrence after CAR-T therapy



CD80/IL2v can maximize efficacy CAR-T therapy

Initial treatment		CAR-T (low)		CAR-T (high)		CAR-T (low) + CD80/IL2v		CAR-T (high) + CD80/IL2v	
Subsequent treatment	Vehicle	CD80/IL2v	Vehicle	CD80/IL2v	Vehicle	CD80/IL2v	Vehicle	CD80/IL2v	Vehicle

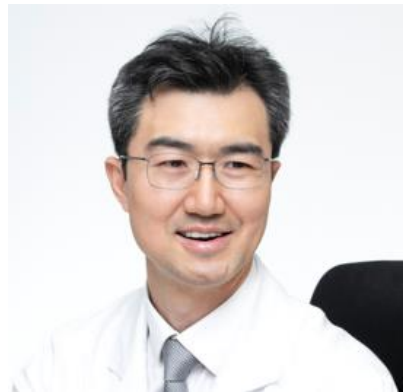
Tumor rechallenge at Day 56 (5×10^5 CD19⁺ Daudi-Luc)
and no further treatment since Day 56



CD80/IL2v as a CAR-T consolidation therapy



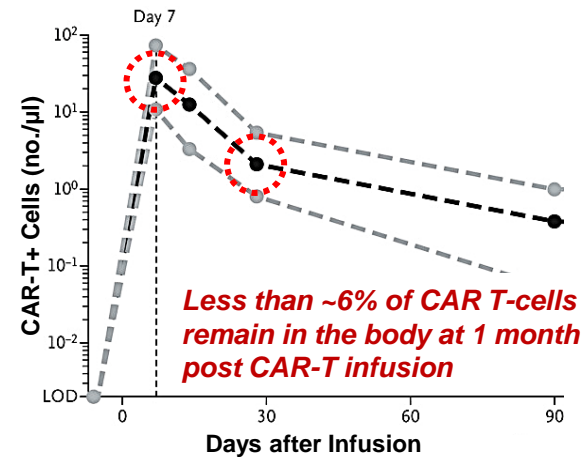
ASAN
Medical Center



Dr. Dok Hyun Yoon

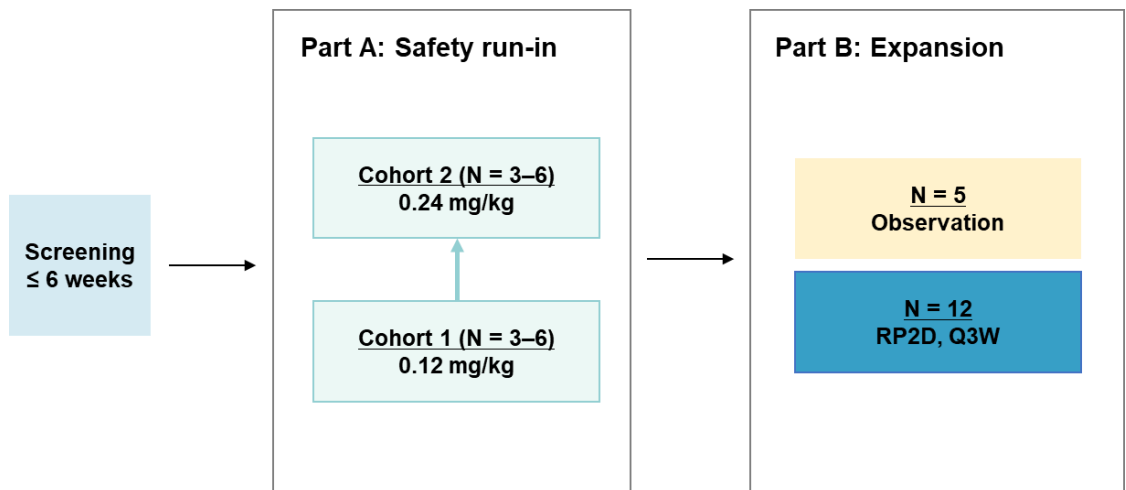
Global KOL
CAR-T Center
Director

CAR-T cell level post treatment



1. Restoration of CAR T expansion
2. To produce better quality CAR T cells to maximize its efficacy

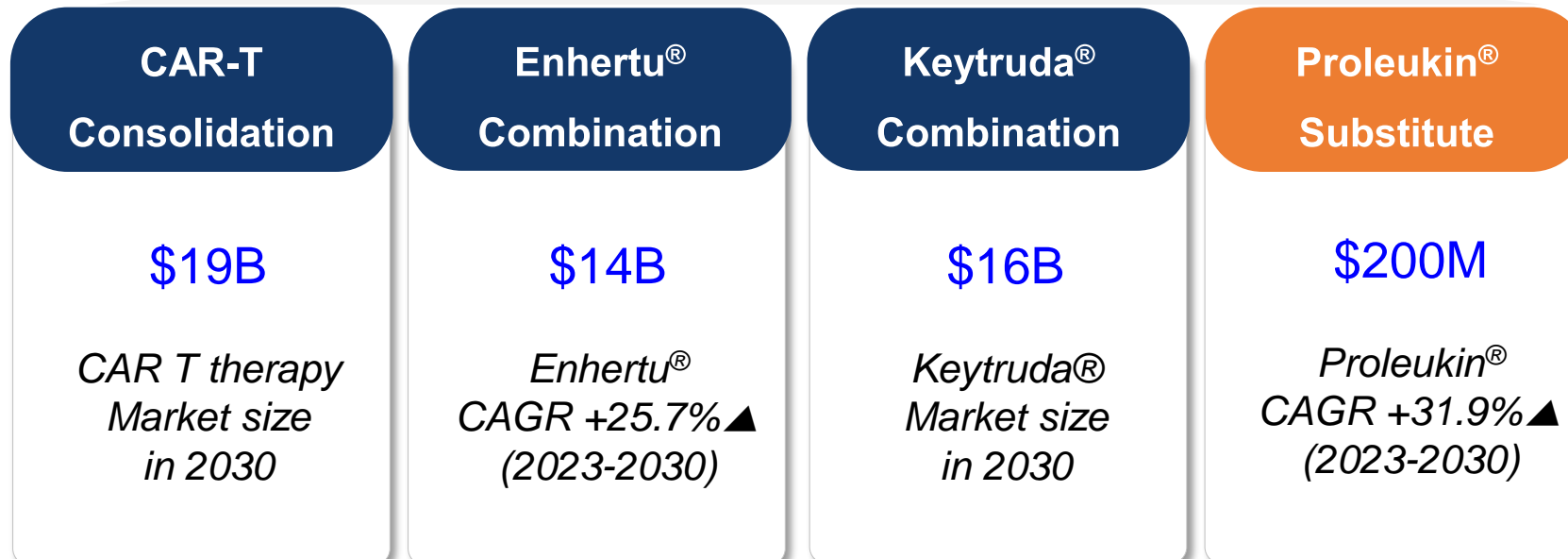
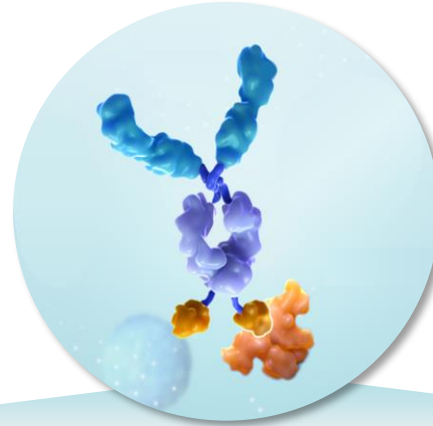
Patients with R/R DLBCL who received CAR-T therapy (N≤29)



Primary objective:
CAR-T re-expansion level

Secondary objectives:
Safety
Efficacy

Key opportunities for GI-101A/GI-102



Predictive market size data from EvaluatePharma

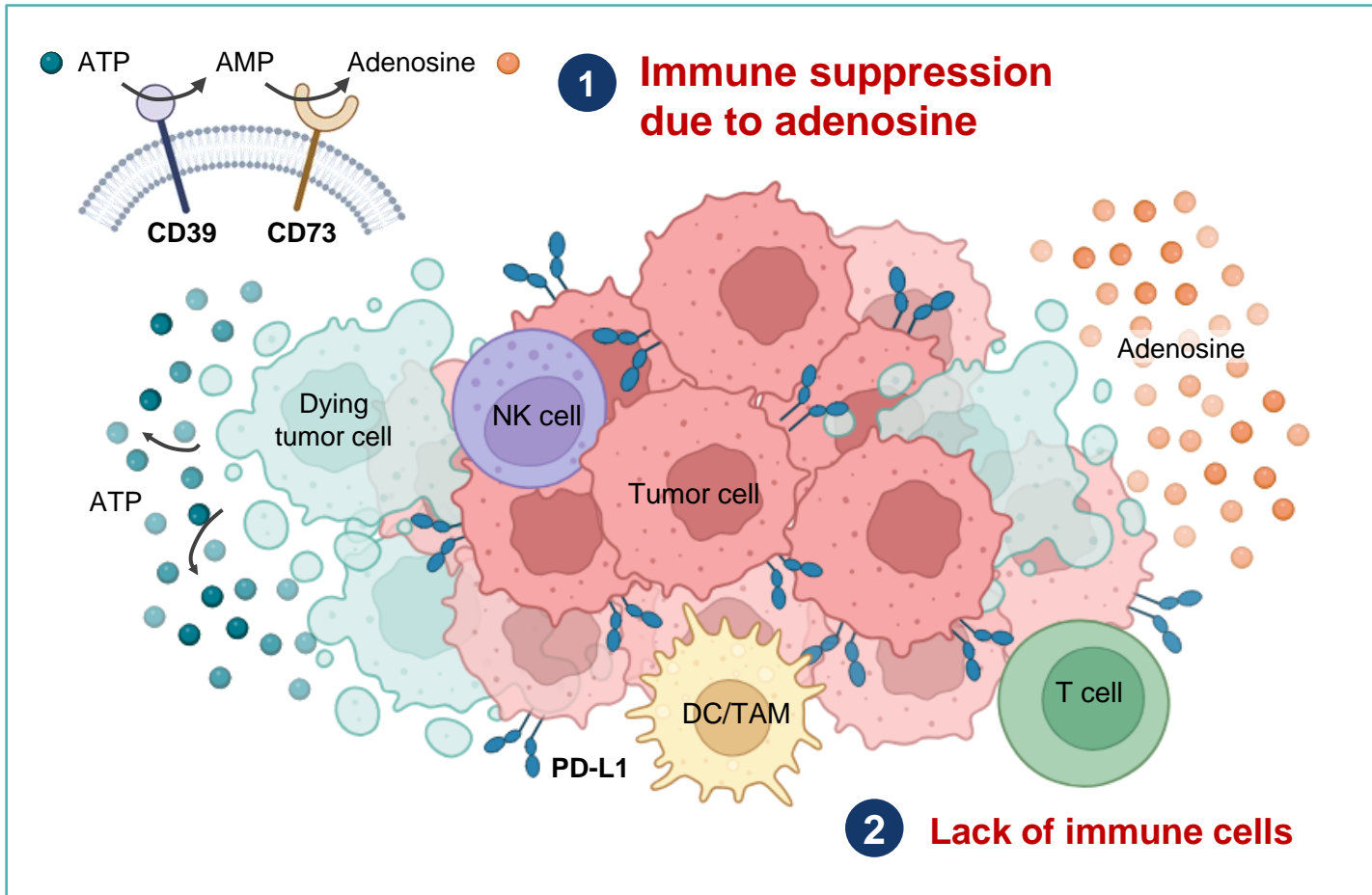


INVESTOR RELATIONS 2024

**Novel bispecific
targeting cancer
metabolism,
'GI-108'**



Targeting tumor metabolism is essential to overcome immunosuppressive tumor microenvironment

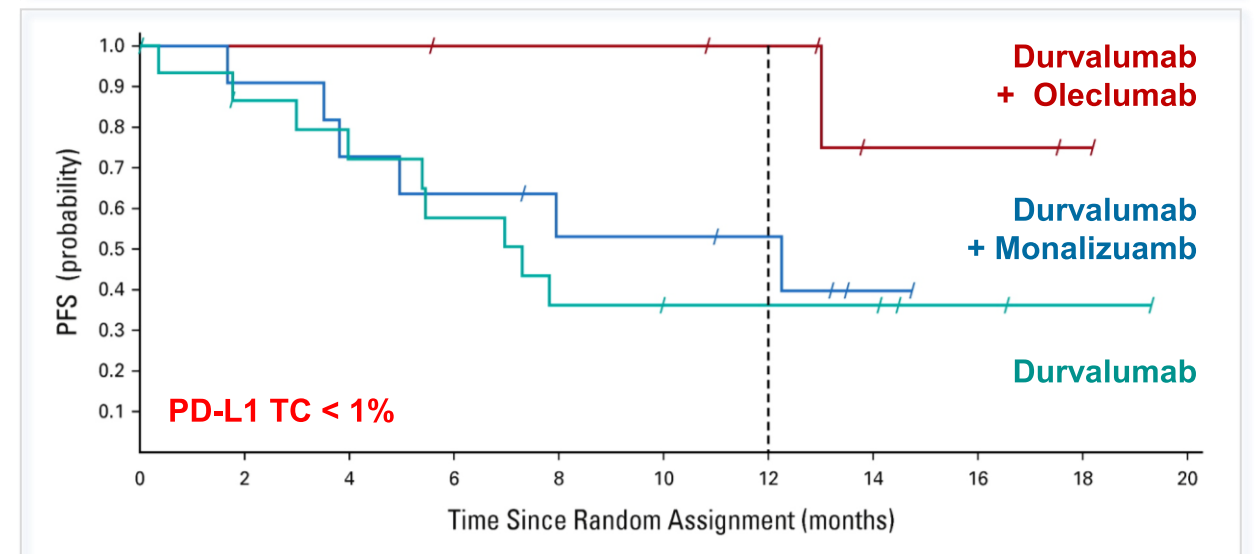
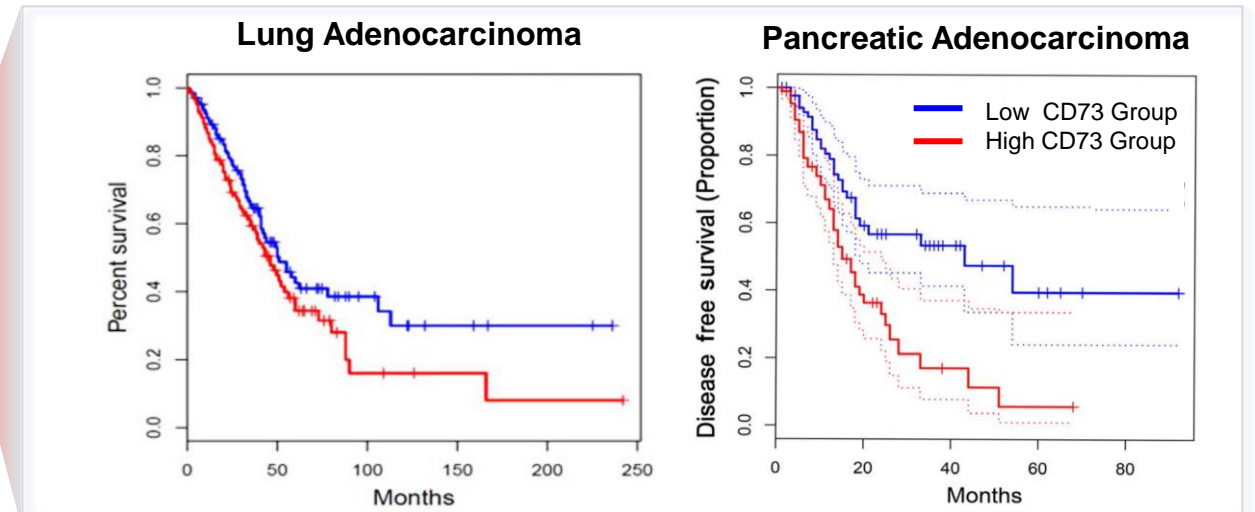


Strategies to overcome adenosine-mediated immune suppression is essential

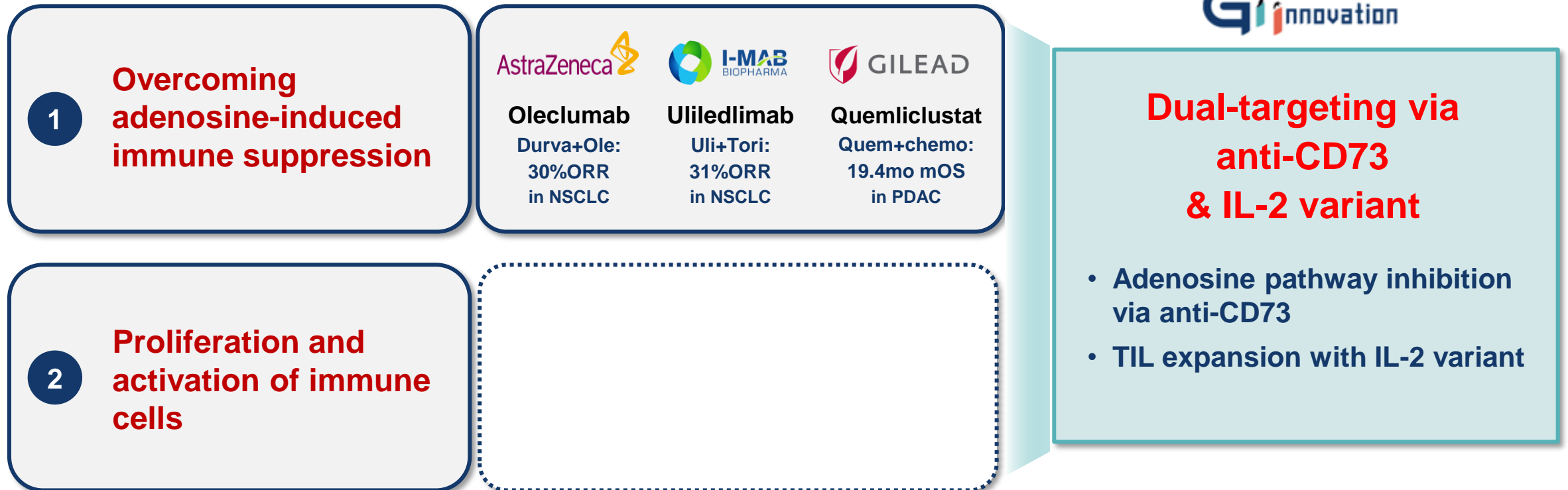
CD73 is a validated target in various cancers

	Target relevance	
Tumor Type	CD73 (NT5E) ¹	Prognosis
Lung Adenocarcinoma	++++	
Pancreatic Adenocarcinoma	+++	
Thyroid Carcinoma	++++	
Sarcoma	++++	
Glioblastoma Multiforme	++++	
Liver Hepatocellular Carcinoma	++++	
Colon Adenocarcinoma	++++	
Rectum Adenocarcinoma	++++	
Stomach Adenocarcinoma	+++	
Brain Lower Grade Glioma	+++	
Esophageal Carcinoma	+++	
Head and Neck Squamous Cell Carcinoma	+++	
Renal Clear Cell Carcinoma	+++	

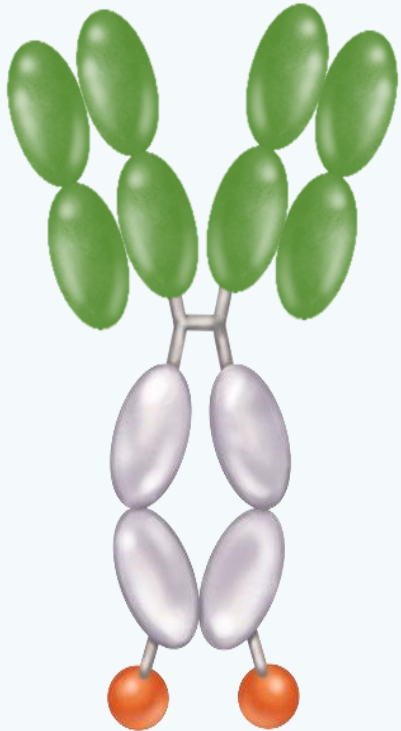
Prognosis
Poor Good



Our approach overcomes the limitation of anti-CD73 antibody



GI-108 has a dual-targeting action via anti-CD73 and IL-2 variant



Anti-CD73

- Targeting of CD73 overexpressing tumor cells
- Inhibits AMP breakdown to adenosine
- Designed to **remediate immune system from tumor-mediated immunosuppression**

IgG4

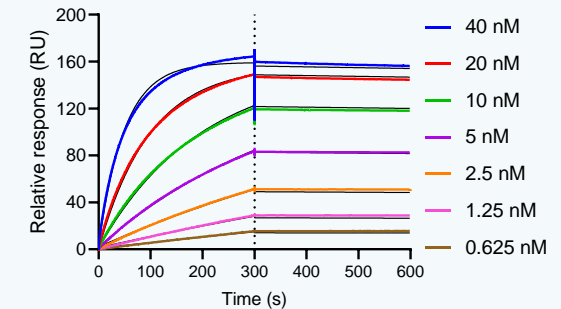
- Low FcγR / C1q Affinity
- No antibody or C-dependent cytotoxicity

IL-2v

- **Substituted 3 amino acids** the wildtype IL-2
- **Removed the affinity to IL-2Rα chain**
- Sustained binding to IL-2 βγ receptors

Binding Affinity to human CD73

	Oleclumab	GI-108
K_D (nM)	0.101	0.089 (x1.2)



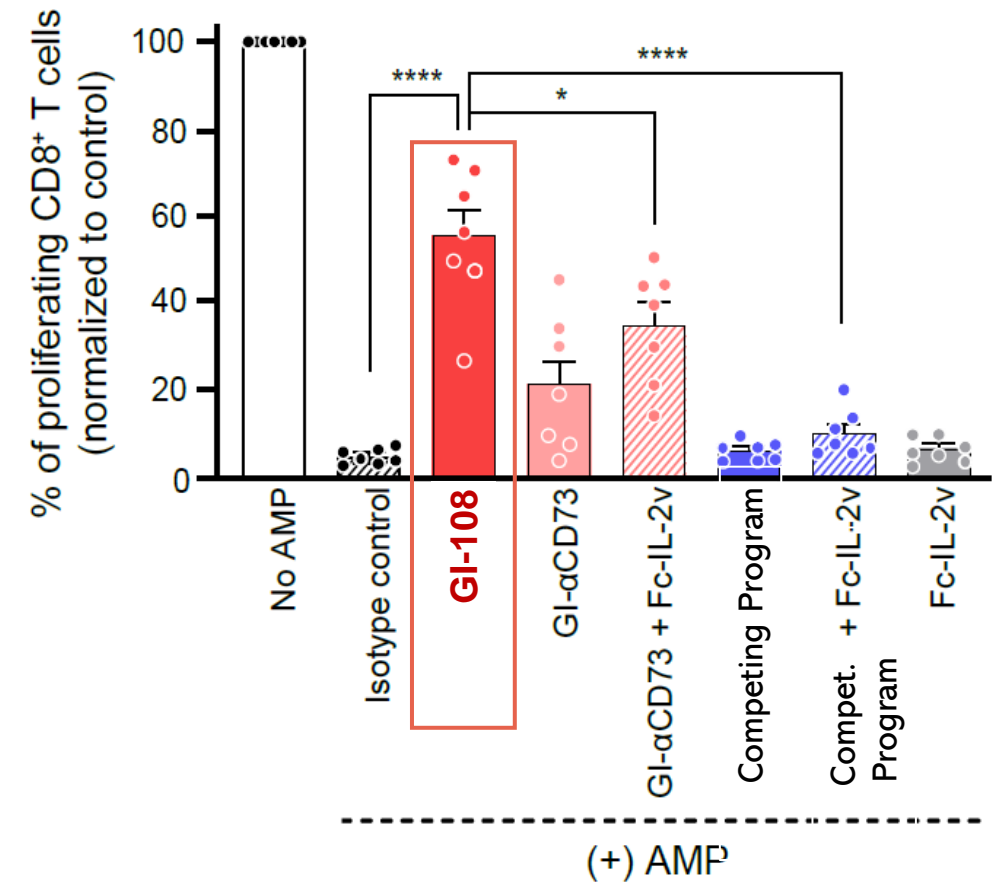
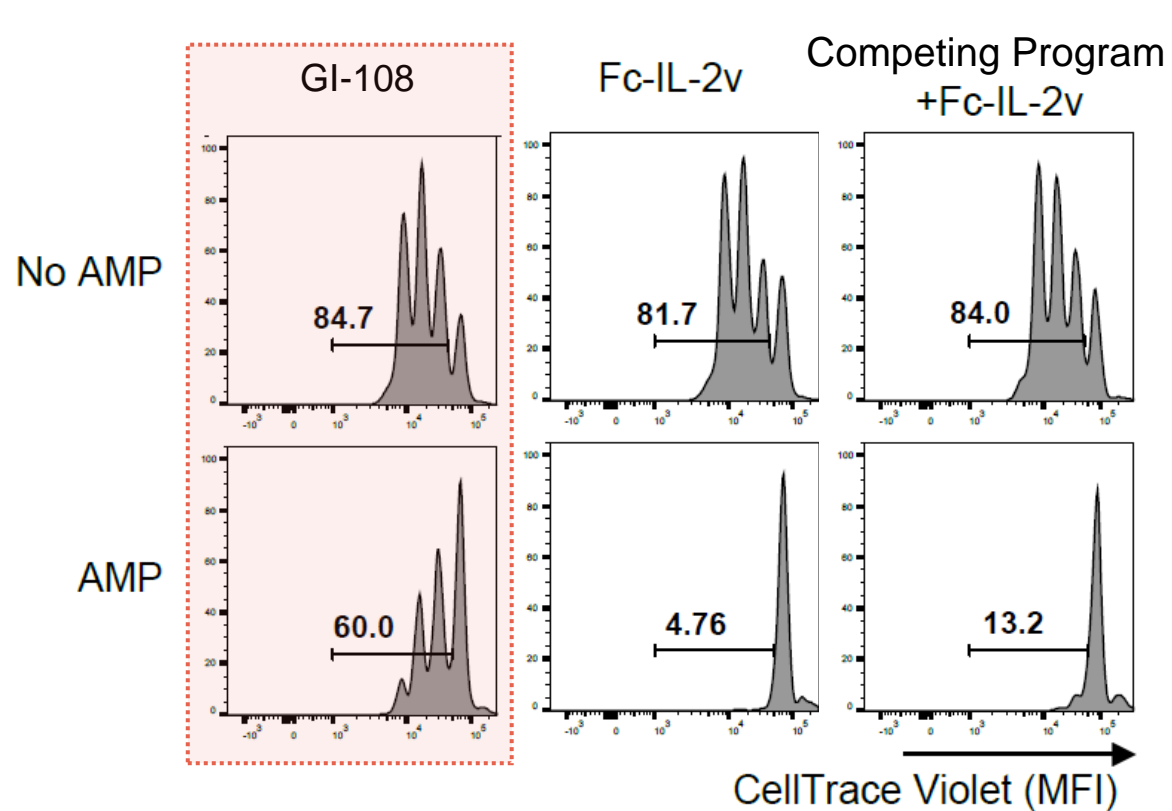
Binding Affinity to IL-2 Receptor (KD, nM)

Receptor	Aldesleukin (IL-2 wild type)	NKTR-214 (2-PEG-IL2)	GI-108 (α-CD73 x IL-2v)
IL-2Rα	49.6 (x42)	486.6 (x8)	N.B.
IL-2Rβ	2080	3951.8	2290
IL-2Rβγ	N/A	N/A	0.2

Source: Stauber et al., PNAS 2006;103:2788-2793, Charyah et al., PLOS ONE 2017;12:e0179431

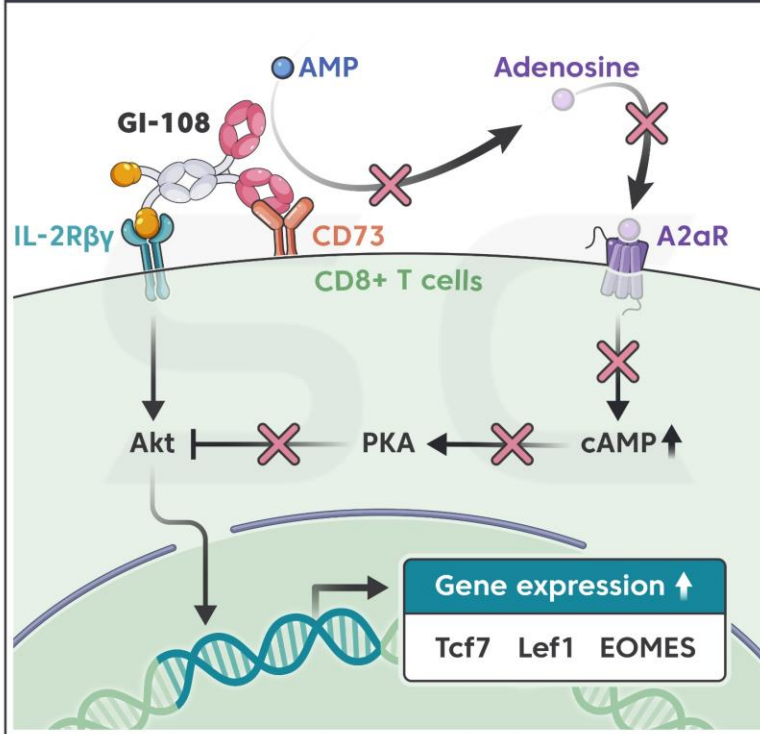
GI-108 reinvigorates CD8+ T cells in AMP-rich conditions

Cell proliferation

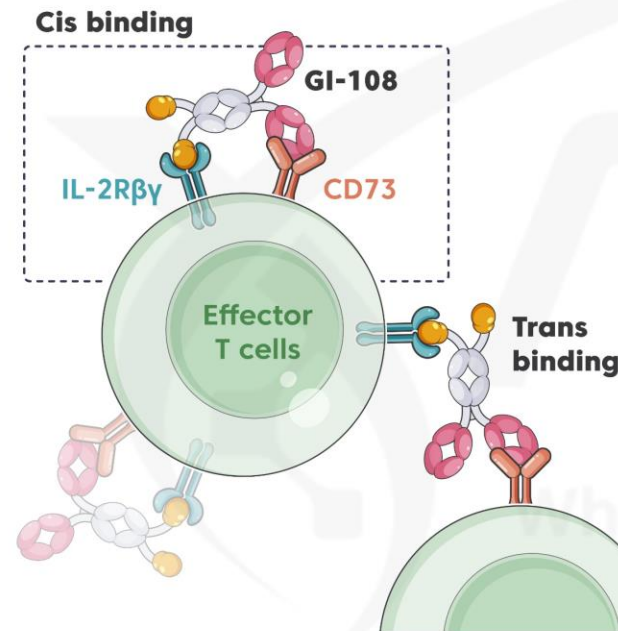


Key competitive edge of GI-108

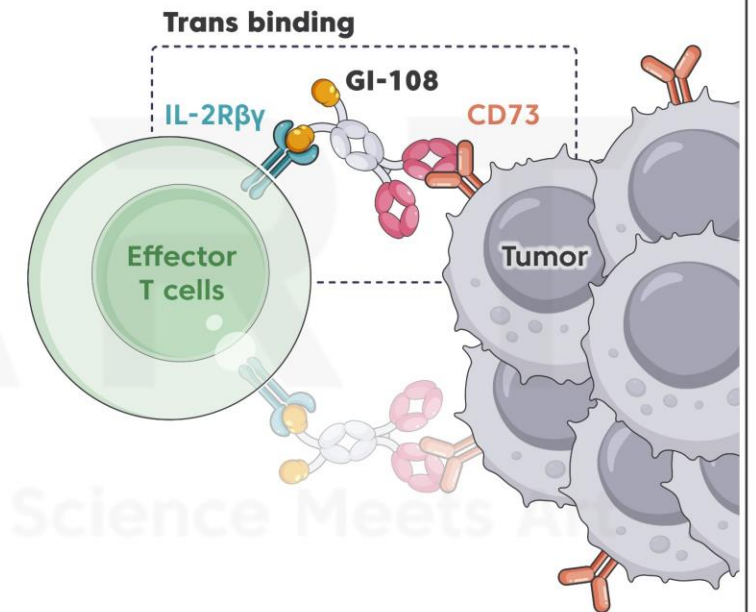
Immune Reinvigoration by CD73 Blockade



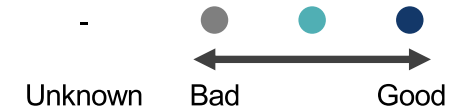
CD8+ T cell Targeting to CD73 and IL-2R $\beta\gamma$ by Cis binding



CD73 Tumor Cell Targeting by Trans binding



GI-108 has superior profiles compared to other anti-CD73 antibody



	Competing Program A	Competing Program B	Competing Program C	GI-108
Description	α-CD73 mAb	α-CD73 mAb	α-CD73 mAb	αCD73/IL2v3
Inhibition of adenosine pathway	V	V	V	V
Tumor targeting	V	V	V	V
Immune cell targeting	V	V	V	V
Proliferation and activation of CD8+ T cells	V	V	V	V
Hook Effect	V	V	-	V

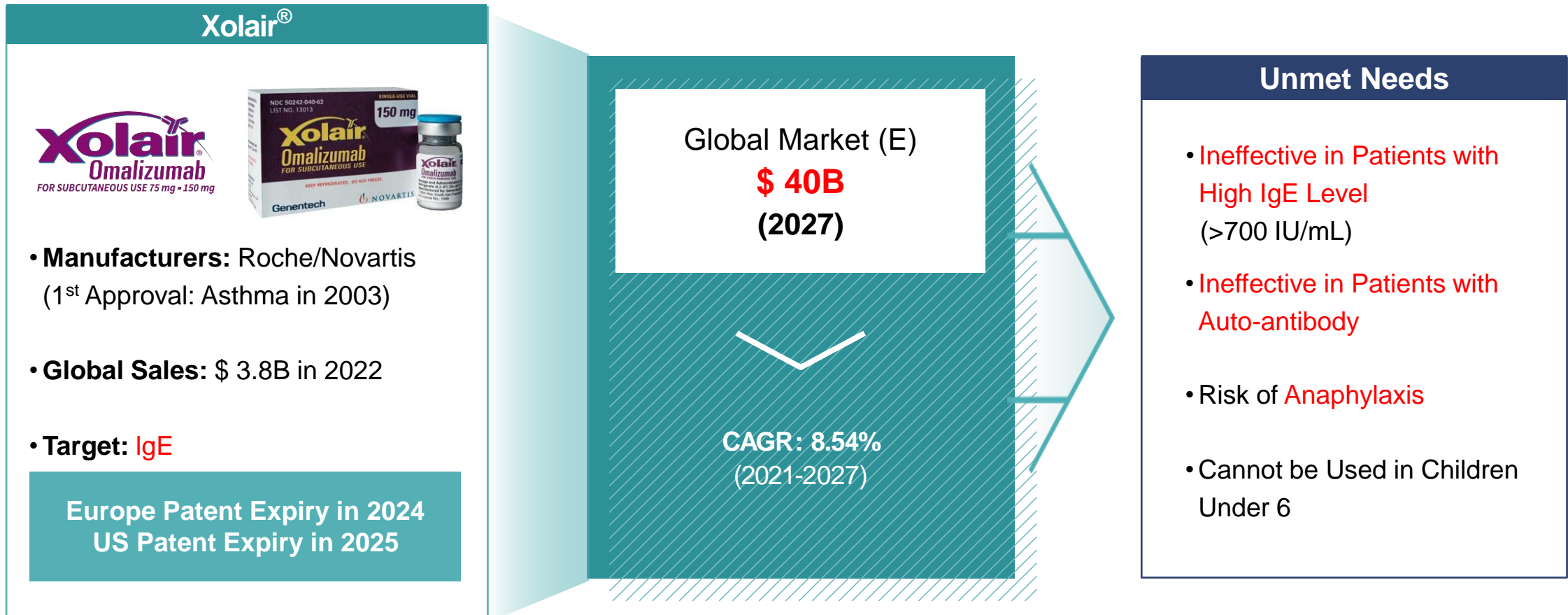


INVESTOR RELATIONS 2024

Next Blockbuster Drug for Allergy, 'GI-301'

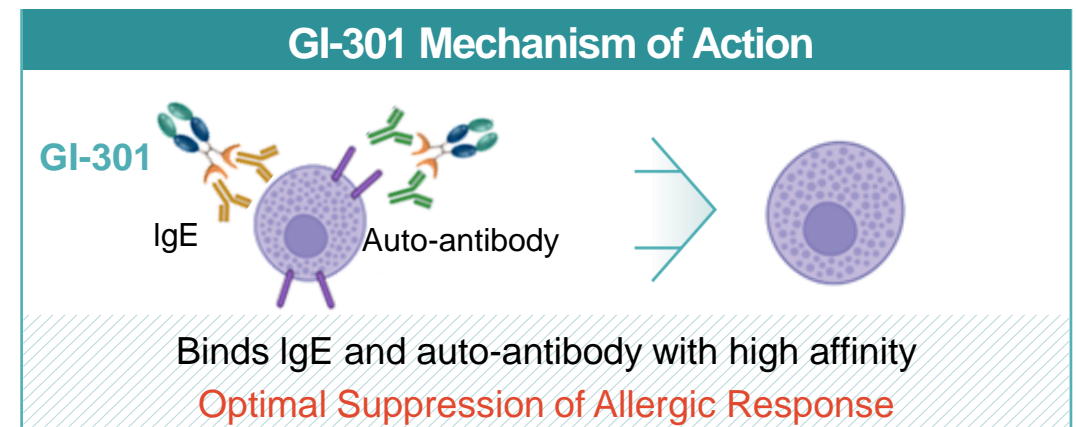
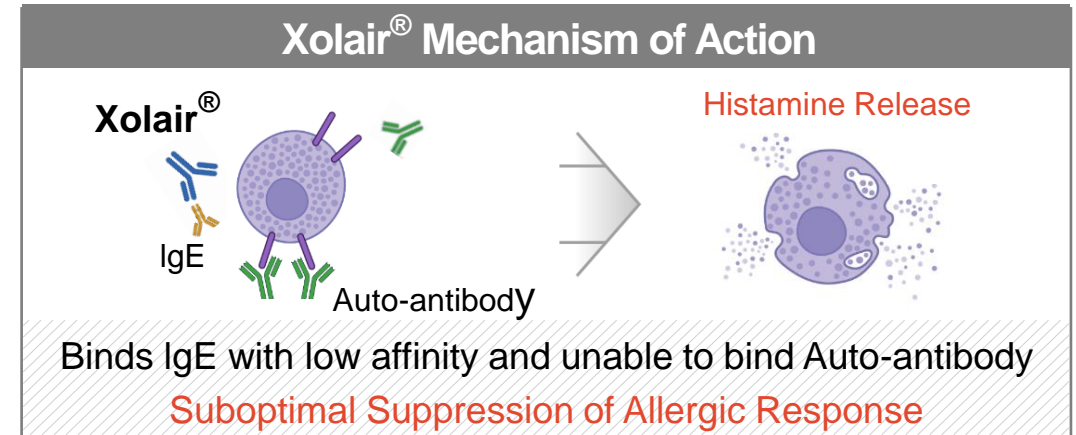
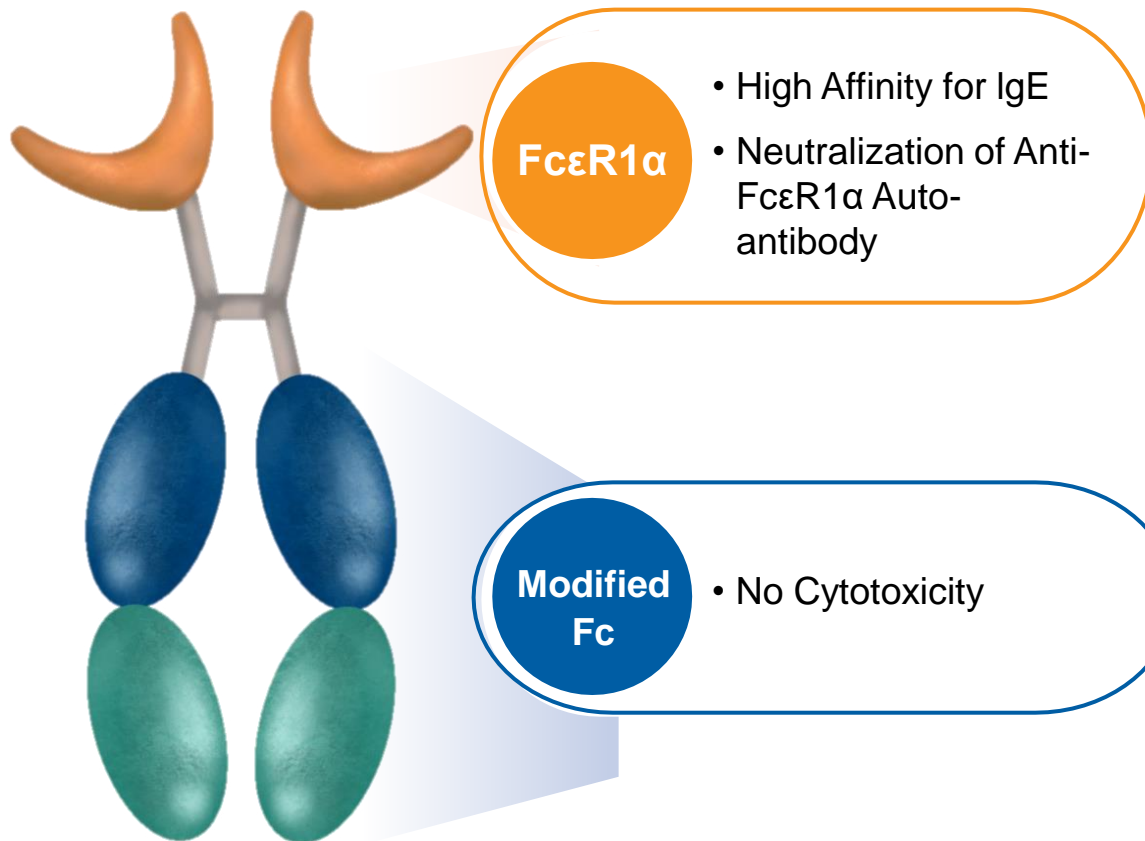


Unmet needs in the allergy market



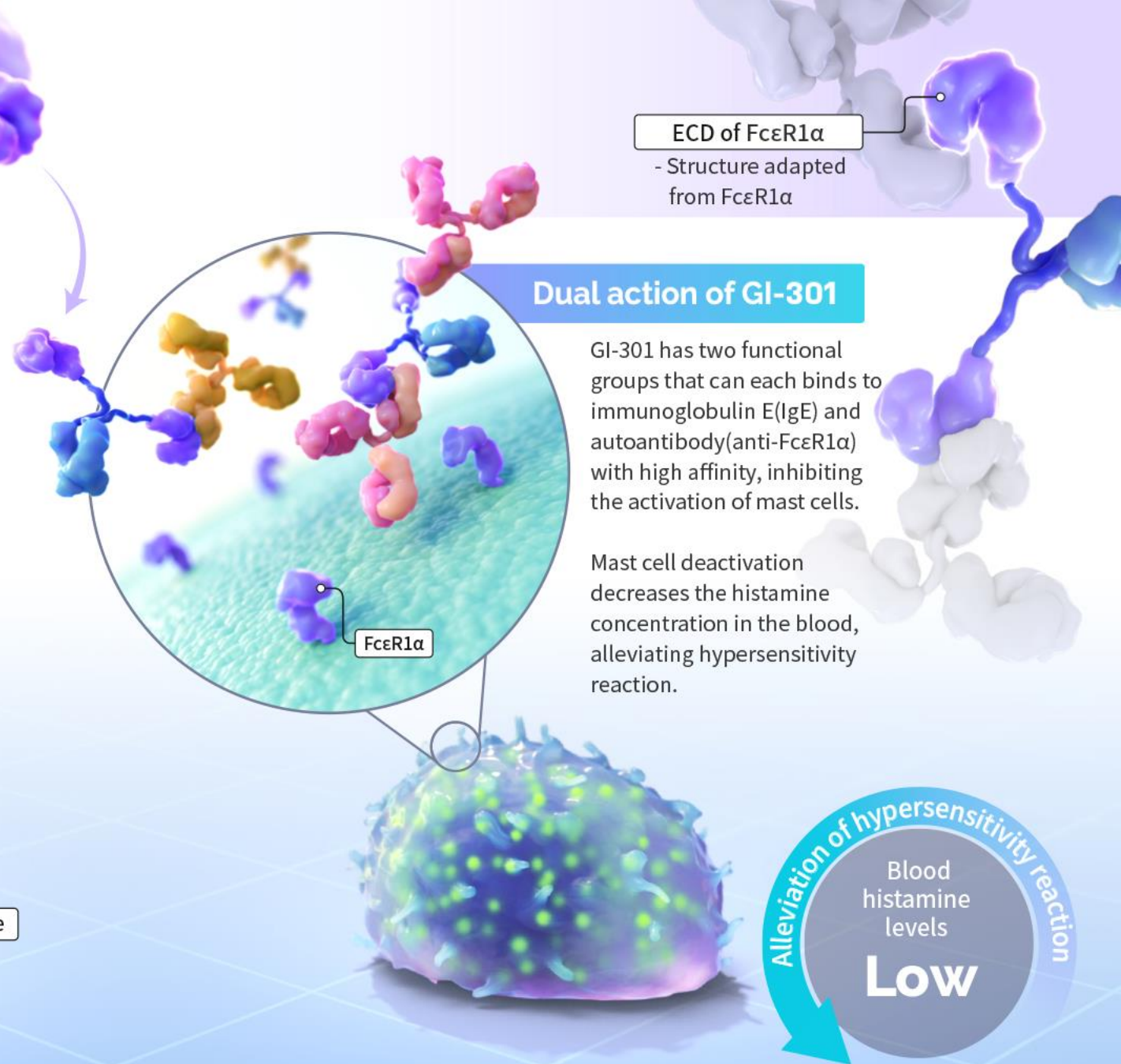
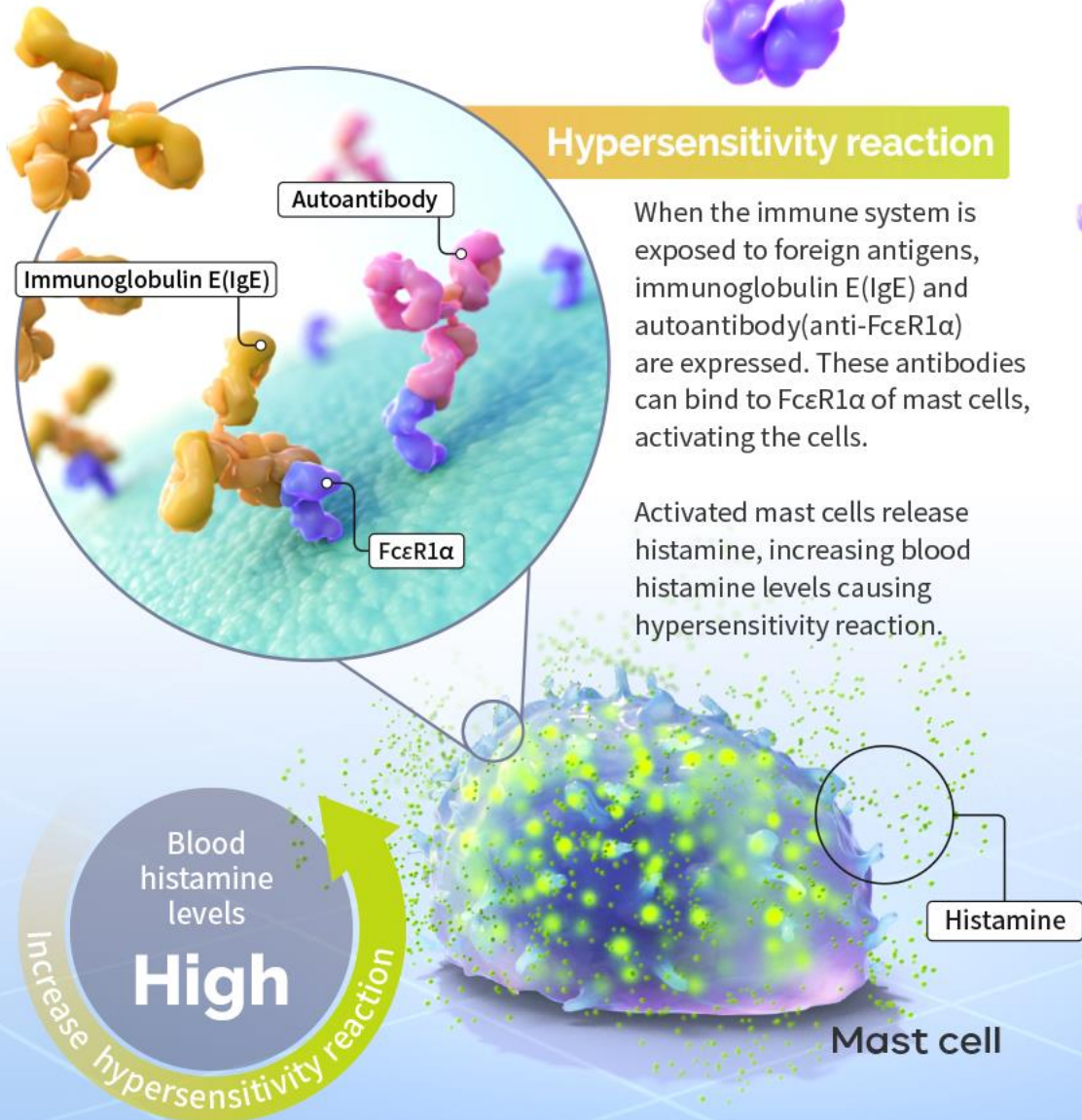
Source: GlobalData, EvaluatePharma (AD, Asthma, Nasal Polyp, Rhinitis, Urticaria, Pruritus, Eosinophilic oesophagitis and Other dermatoses; Sales and Forecasts 2021-2027)

Novel IgE trap, GI-301 blocks IgE and auto-antibody

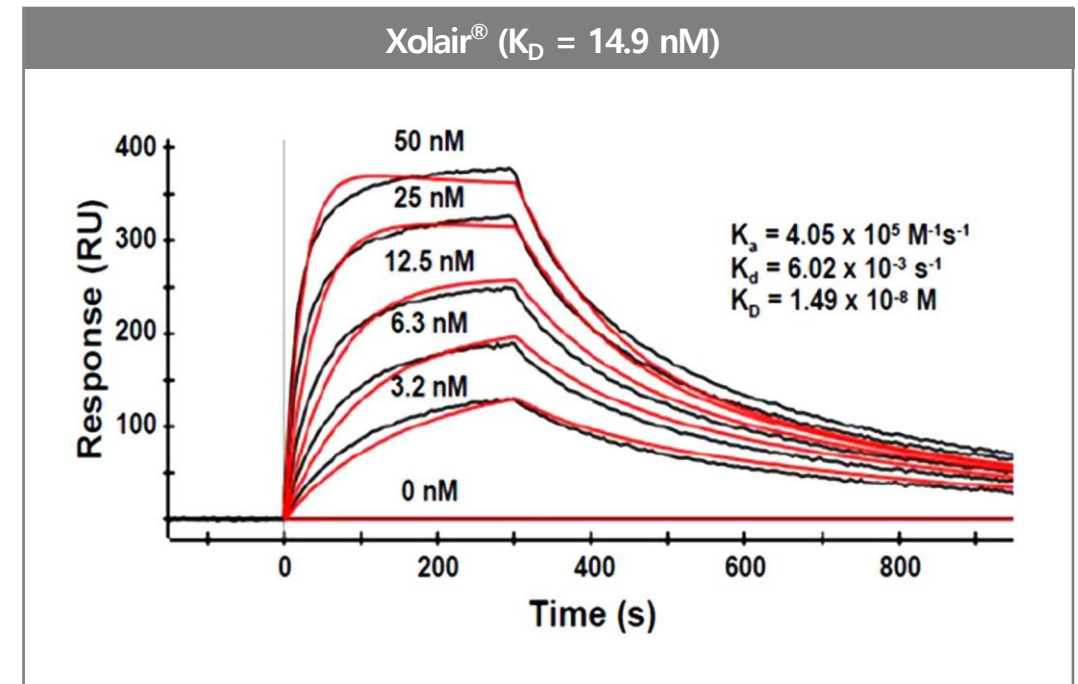
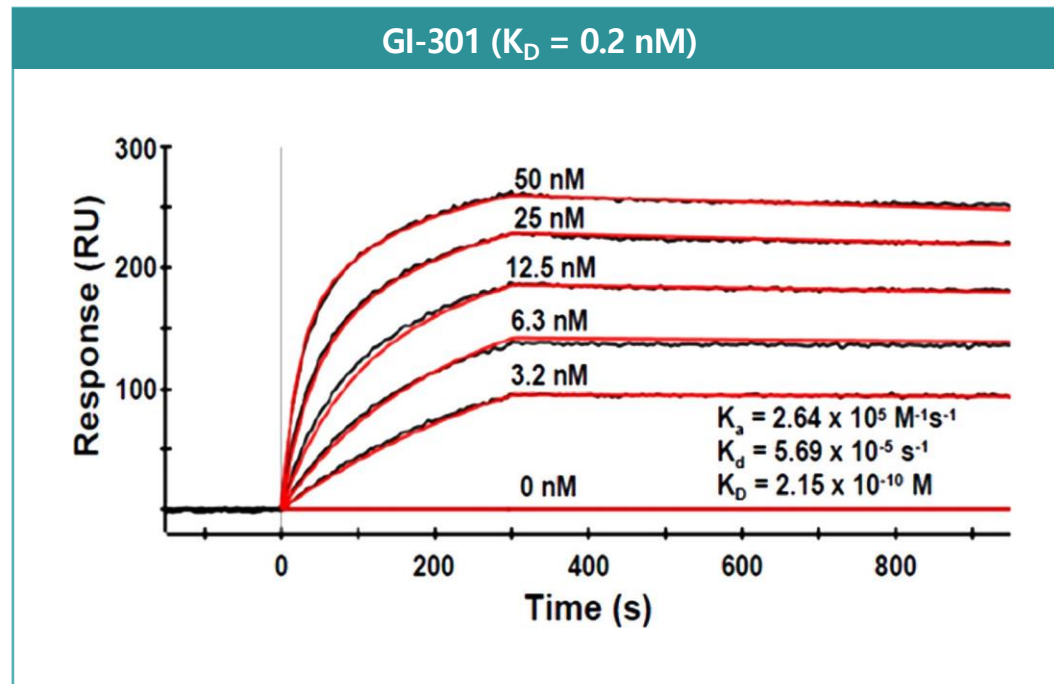


MoA of GI-301




GI-301 in hypersensitivity reaction



GI-301 binds IgE approximately 70 times higher than Xolair®



Superior to competitive products

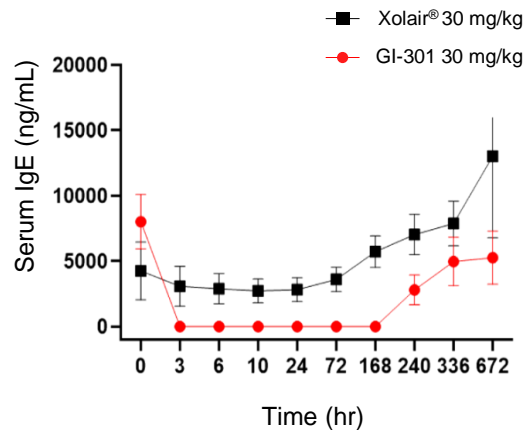
				
Category	Function	GI-301 (FcεRIα-Fc)	Xolair® (anti-IgE antibody)	Ligelizumab (anti-IgE antibody)
Efficacy	IgE Affinity	●	○	●
	Auto-antibody	● Effective	○ Not Supported by MOA	○ Not Supported by MOA
Safety	Low Risk of Anaphylaxis	●	○	○

●: High ◐: Intermediate ○: Low

GI-301 better controls IgE level than omalizumab across all dosing range

Greater IgE reduction, longer effectiveness than Xolair® after single dose

Preclinical NHP Study

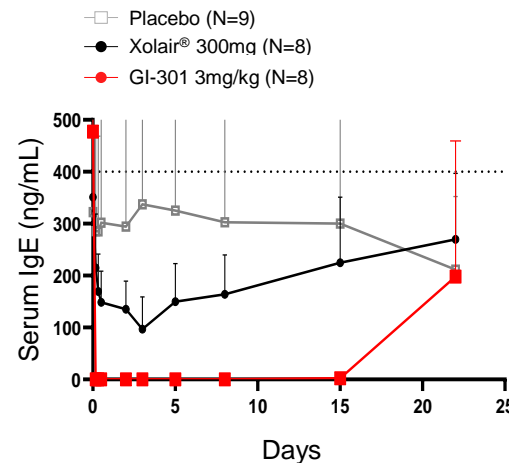


Baseline free IgE (ng/mL)

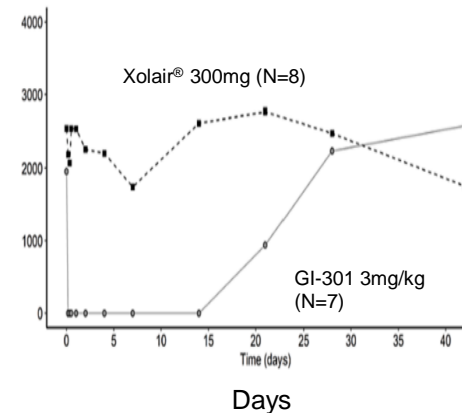
Xolair®	4,264 ± 2,215 (1,777 ± 923 IU/mL)
GI-301	8,024 ± 2,066 (3,343 ± 861 IU/mL)

Ph Ia Clinical Data

IgE 30-700 IU/mL



IgE > 700 IU/mL¹⁾



Days maintaining IgE level < 25 ng/mL

Xolair®	0
GI-301	18.5

Days maintaining IgE level < 25 ng/mL

Xolair®	0
GI-301	15



Prof. Marcus Maurer

- Charite hospital in Germany
- Coordinating Investigator of Xolair®, Ligelizumab

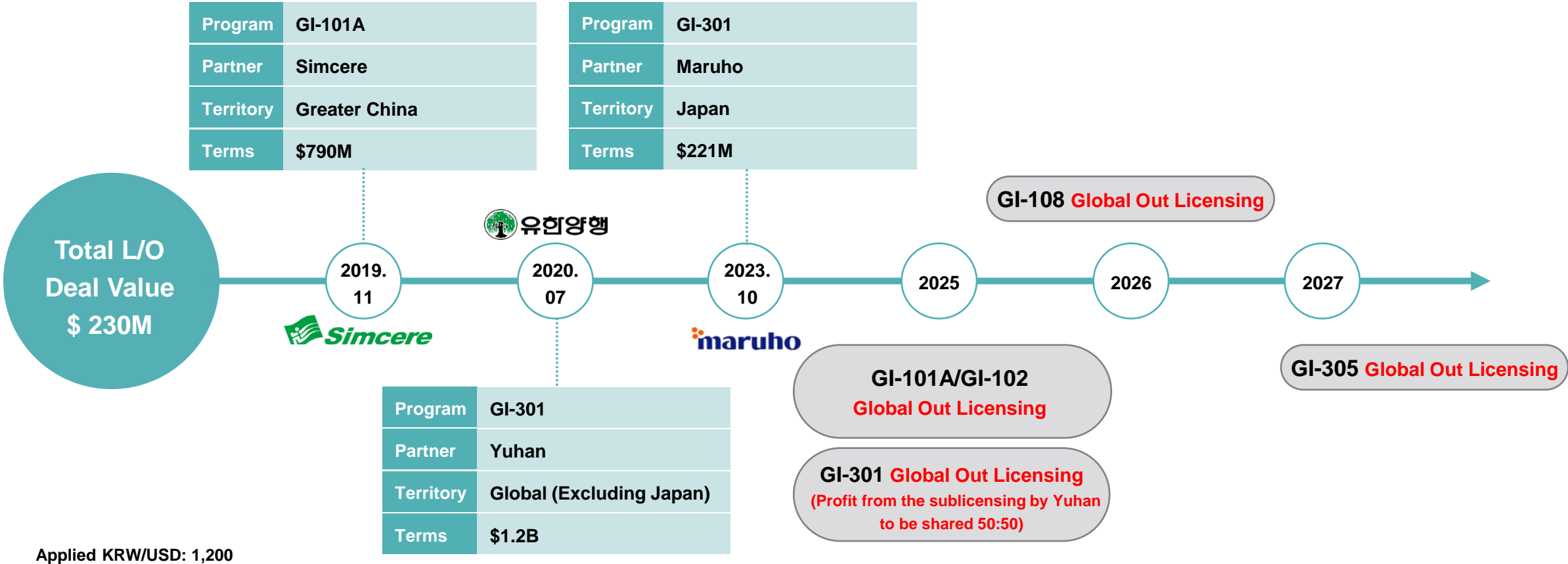
**nature
REVIEWS
IMMUNOLOGY**

October 2021

“GI-301 exhibits higher and more durable binding to IgE than omalizumab (Xolair®)”

Marketability

4 new deals in the next 4 years and targeting product commercialization





ir@gi-innovation.com