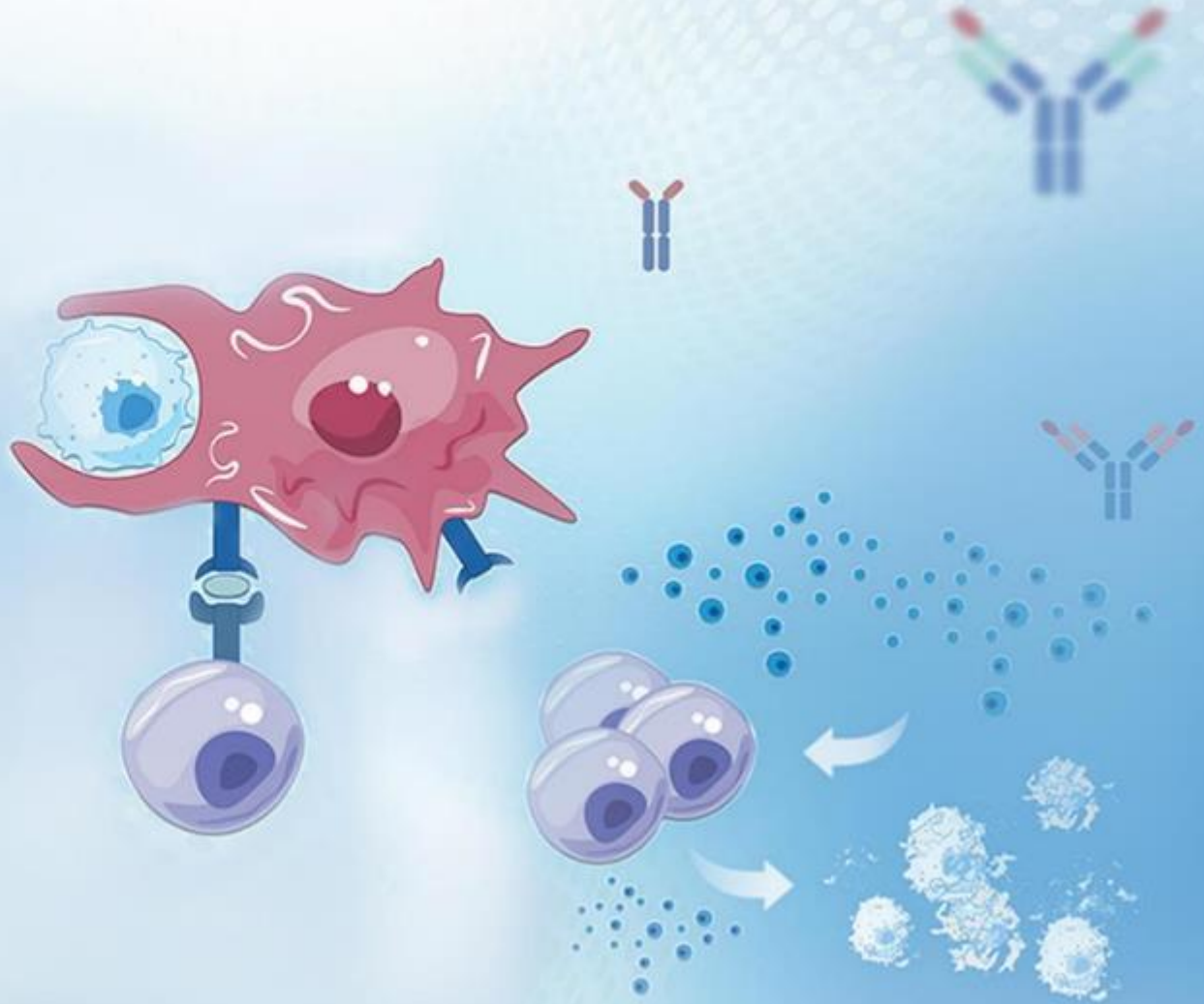
宜明昂科
ImmuneOnco

Corporate Presentation

May 2025



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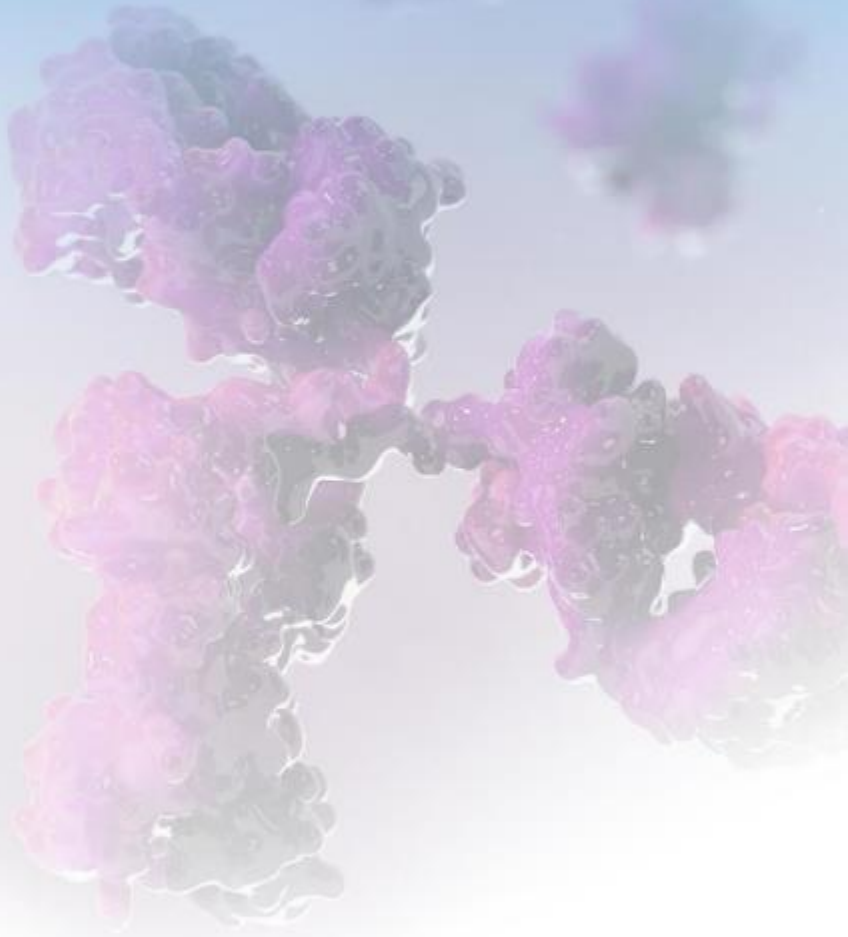
SECTION 1

Company Overview



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Key Milestones

- Steady team with **10+** years coordination
- **30** issued patents
- **26** pending patent applications
- **30** IND approvals from the NMPA and the FDA
- **11** ongoing clinical programs

Pipeline

2015-2020

- 2015: ImmuneOnco was incorporated in the PRC
- 2019: The first patient of the Phase I clinical trial for **IMM01** was enrolled
- 2019: IND approval for **IMM0306** from NMPA
- 2020: Established the **pilot production line** with 200L GE single-use mammalian cell bioreactors
- 2020: IND approval for **IMM2510** from NMPA

2021

IMM01:
- IND approval by NMPA for the Phase Ib/II in with each of azacitidine and inetetamab
- Phase II initiation for IMM01 monotherapy

IMM0306:
- IND approval by FDA

IMM2902:
- IND approval by NMPA and FDA

IMM27M:
- IND approval by NMPA

2022

IMM01:
- Phase II in combination with either PD-1 mAb or azacitidine commenced in China

IMM2902:
- Phase I dosed patients in both China and US

IMM27M:
- Phase I trial patients dosed in China

IMM40H & IMM2520:
- IND approval by NMPA and FDA

2023

IMM01:
- Orphan drug designation in the U.S.

IMM0306:
- Phase Ib/IIa initiation in China in combination with lenalidomide and dosed its first patient

IMM2510:
- Phase I dose escalation LPI and RP2D determined
- IND approved for IMM2510+ chemo and IMM2510+ IMM27M in China
- Phase II monotherapy for R/R STS dosed first patient

IMM27M:
- Phase I dose escalation LPI and RP2D determined in China

IMM47:
- IND approval by NMPA
- Dosed first patient in Australia

2024

IMM01:
- Three phase III clinical trials approved for MDS, CMML and cHL in China
- Phase III cHL & CMML dosed first patient

IMM0306:
- Phase II of IMM0306+ lenalidomide initiated for advanced R/R FL
- Phase Ib of IMM0306+ lenalidomide for R/R DLBCL dosed first patient
- SLE& NMOSD dosed first patient

IMM2510:
- Phase Ib in combination with IMM27M for solid tumors dosed first patient
- Phase Ib/II in combination with chemo for 1L NSCLC first patient
- Reached a license-out agreement of US$2.1B with Instil Bio

2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024

Financing

2017: Series Pre-A, RMB30 MM	2018: Series A, RMB90 MM	2020: Series Pre-B, RMB40 MM	2020: Series B, RMB240 MM	2021: Series B+, US$65 MM	2022: Series C, US$87.5 MM	2023: IPO, US$43 MM	2024: Placement, US$30 MM

Key Investors

Lilly Asia Ventures 礼来亚洲基金 · LYFE CAPITAL · 龙磐投资 LAPAM CAPITAL · 上海科创基金 Shanghai Sci-Tech Innovation Center Capital · 阳光保险集团 Sunshine Insurance Group · 南京星健睿赢 · 荣昌股权投资

Total amount of fund raised: ~$285MM

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Integrated proprietary R&D platform

Efficiently Conduct Screening and Druggability Analysis → Optimize Molecule Structure Design → Cost-effectively Manufacture High-quality Drug In-house → Next-generation Innovative Oncology Therapies

Target Selection and Validation

Drug Discovery

High-throughput Screening

Molecule Design

Preclinical Studies

CMC and IND-enabling Capabilities

Clinical Development

Integrated in-house R&D Platform

Advanced Hybridoma Technology	High-throughput Screening	Proprietary mAb-Trap Bispecific Platform	Strong Immunoassay and Bioassay Technology	Efficient Cell Line Development	Robust CMC and Manufacturing Capacity
• Efficiently identify and improve antibody fragments with higher specificity, affinity and other best-suited properties		• Allowing for favorable binding affinity with tumor targets while preserving IgG1 Fc effector function • Ease of manufacturing, product stability, higher tier and protein yield			• Our stable R&D, CMC and regulatory affairs teams with ~60 members

Global Rights

- **30** IND approvals from the NMPA and the FDA
- **30** Issued patents
- **26** Pending patent applications

Pilot manufacturing: 200L/250L bioreactors

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Comprehensive Pipeline Covering Oncology and non-Oncology Therapeutic Areas

Program [1]	Target (Modality)	Indication(s)	Discovery	Preclinical	IND/IND-Enabling	Phase Ia/I	Phase Ib/II	Phase III/ Pivotal	Partners	Current Status / Upcoming Milestone	Commercial Rights
IMM01 （timdarpacept）											
IMM01 + Azacitidine	CD47 (SIRPα-Fc fusion protein)	MDS[2]	China (NMPA)							Received Phase III approval from CDE in May 2024	Global
IMM01 + Azacitidine	CD47 (SIRPα-Fc fusion protein)	1L CMML	China (NMPA)							Received Phase III approval from CDE in June, FPI in November 2024	Global
IMM01 + Tislelizumab	CD47+PD-1	cHL[3]	China (NMPA)							Received Phase III approval from CDE in April; FPI in July 2024	Global
IMM01 + IMM2510	CD47+VEGFxPD-L1	Solid Tumors	China (NMPA)							Received Phase Ib/II approval from CDE in March 2025	Global
IMM2510 （palverafusp alfa） Monotherapy	VEGFxPD-L1 (Bispecific)	Solid Tumors	China (NMPA)						InstilBio	Phase Ib/II commenced in November 2023 in China	Great China
IMM2510 + Chemo	VEGFxPD-L1 (Bispecific)	1L NSCLC	China (NMPA)						InstilBio	IND approved in China in November 2023, FPI in December 2024	Great China
IMM2510 + Chemo	VEGFxPD-L1 (Bispecific)	1L TNBC	China (NMPA)						InstilBio	IND approved in China in November 2023	Great China
IMM2510 + IMM27M	VEGFxPD-L1 (Bispecific) + CTLA-4	Solid Tumors	China (NMPA)						InstilBio	IND approved in China in October 2023, FPI in July 2024	Great China
IMM27M （tazlestobart）	CTLA-4 ADCC+ (mAb)	Solid tumors	China (NMPA)						InstilBio	Phase Ia completed in September 2023 in China，FPI for Phase Ib HR+ mBC in September 2024	Great China
IMM0306 (amulirafusp alfa) IMM0306 + Lenalidomide	CD47xCD20 (Bispecific)	R/R FL&MZL	China (NMPA)							Phase Ib/IIa commenced in June 2023 in China，LPI for FL cohort in December 2024	Global
IMM2520	CD47xPD-L1 (Bispecific)	Solid tumors	China (NMPA)，US (FDA)							IND approved in China and the U.S. in Q4 2022; Phase I commenced in China in March 2023	Global
IMM0306 (amulirafusp alfa)	CD47xCD20 (Bispecific)	SLE	China(NMPA)							FPI in October 2024	Global
		NMOSDs	China(NMPA)							FPI in December 2024	Global
		LN	China(NMPA)							IND approved in China in December 2024	Global
IMM01 （timdarpacept）	CD47 (SIRPα-Fc fusion protein)	Atherosclerosis								IND-enabling	Global
IMC-003 (IMM72)	ActRIIA (Fc-fusion protein)	PAH, Undisclosed	China(NMPA)							IND submitted	Global
IMC-010 (IMM7220)	GLP-1xActRIIA (Bispecific)	Obesity (lose fat and build muscle)								In vivo efficacy study is ongoing	Global

Innate Immunity Targets | **Innate and Adaptive Immunity Targets** | **Adaptive Immunity Targets** | **CV, autoimmune, metabolic disease**

Notes:
(1) All of the Company's clinical- and IND-stage drug candidates are classified as Category 1 innovative drugs, and preclinical- and discovery-stage drug candidates are expected to be classified as Category 1 innovative drugs, in accordance with relevant laws and regulation in China
(2) The trial is mainly designed to target the first-line treatment of higher-risk MDS (patients who fall into higher-risk group categories in the original or revised International Prognostic Scoring System).
(3) This combination of IMM01 and tislelizumab targets prior PD-(L) 1-refractory cHL.

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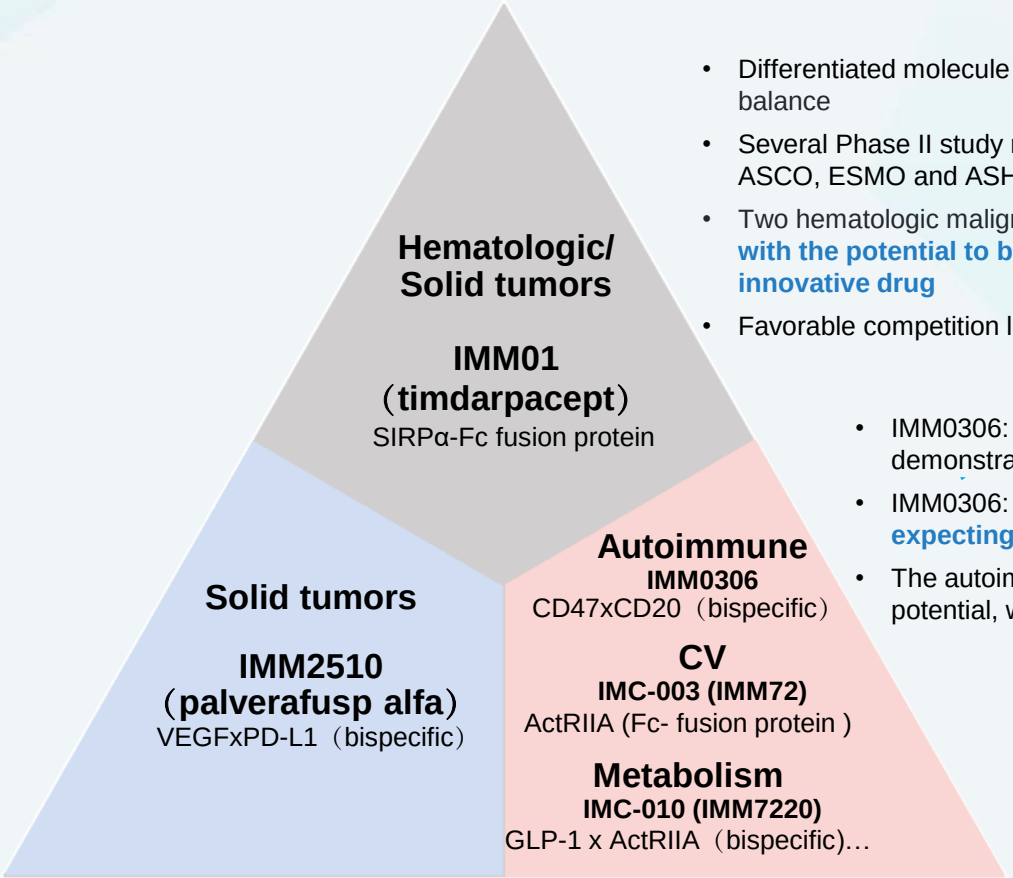
Three Strategic Product Matrices Support Future Growth

We have matured proprietary R&D platform and comprehensive innovation pipeline portfolio



- Differentiated molecule design to achieve optimal safety and efficacy balance
- Several Phase II study results were selected for oral presentation at ASCO, ESMO and ASH
- Two hematologic malignancy indications have advanced to phase III, **with the potential to become the first approved CD47-targeted innovative drug**
- Favorable competition landscape and with enormous market potential

- The Phase III clinical trial data of a peer molecule demonstrated strongly positive results in a head-to-head comparison against Keytruda, proving the immense potential of VEGFxPD-(L)1 bispecific molecules
- Clinical progress ranks in the first echelon
- The combination therapy with chemo for 1L NSCLC has entered phase Ib/II, **expecting the preliminary data readout in 2H 2025**

- IMM0306: B-cell depletion without cytokine storm demonstrates a favorable safety profile
- IMM0306: SLE and MNOSD advanced to phase Ib/II, **expecting the preliminary data readout in mid-2025**
- The autoimmune disease field has enormous market potential, with international BD collaborations booming

- **IMC-003 is anticipated to receive IND approval for PAH in mid-2025,** with a leading position in clinical development progress

- Multiple new-generation candidates targeting ActRIIA/B, **with strategic in-depth layout in obesity (lose fat and build muscle)**

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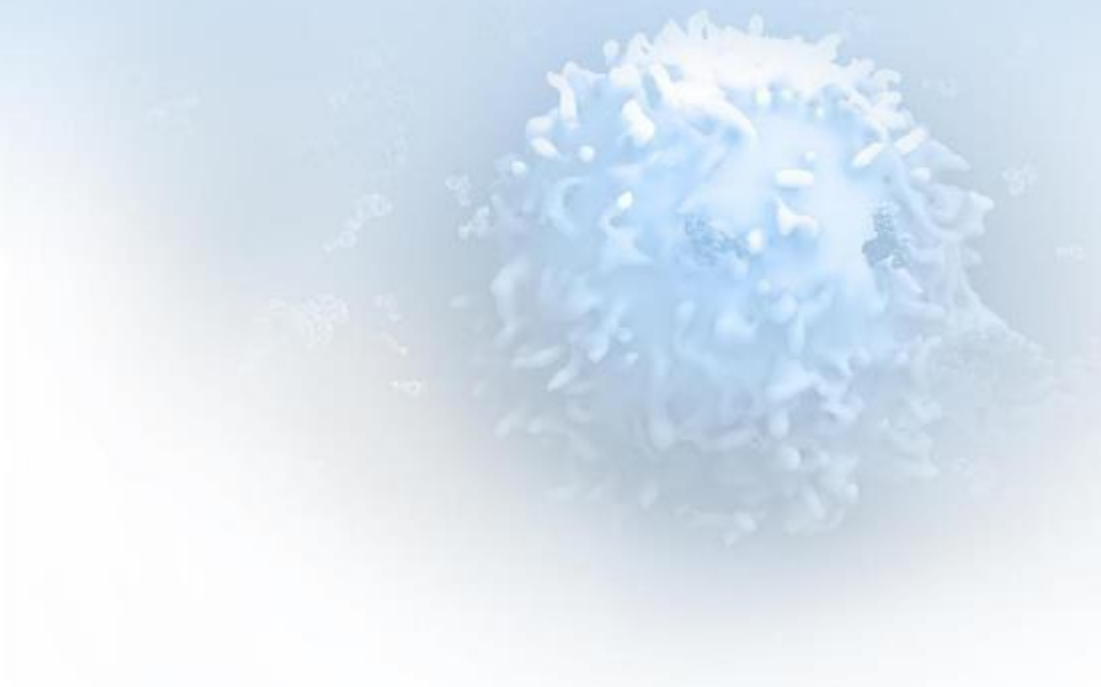
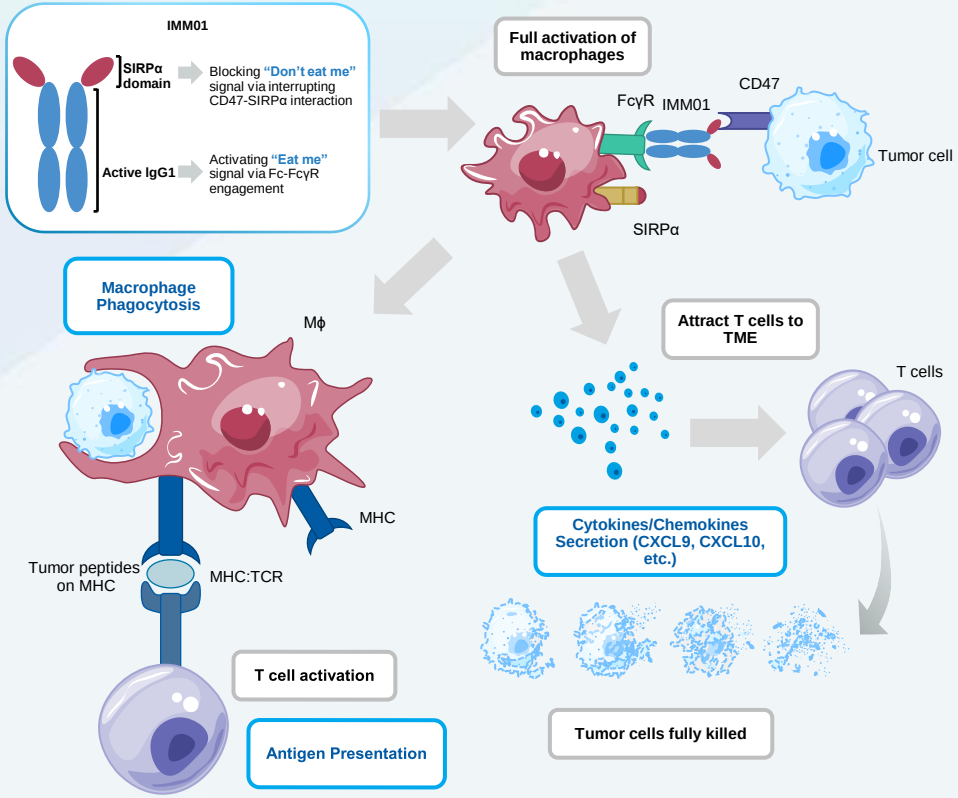
SECTION 2

Major Oncology Programs



IMM01(timdarpacept)

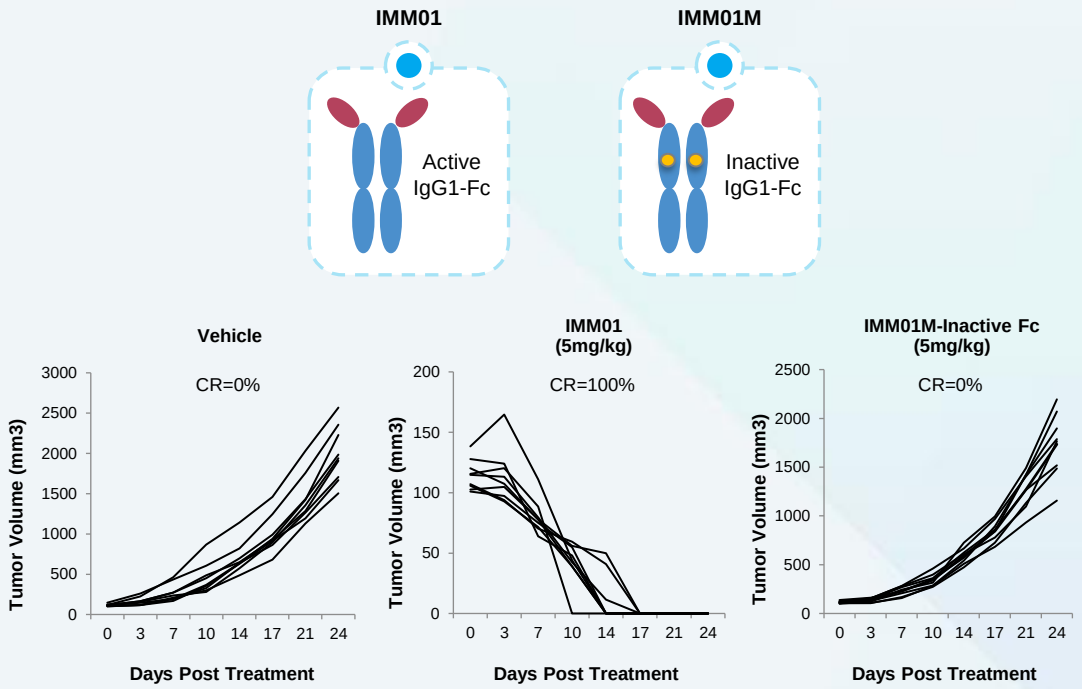
Overview and Competitive Advantage of IMM01(Timdarpacept)



Notes:
MHC refers to major histocompatibility complex

Source: Company Data

In Vivo Efficacy of IMM01 is Dependent on Effective Fc Function (HL-60 xenograft model)



Notes: IMM01M has an engineered mutant inactive IgG1 Fc.

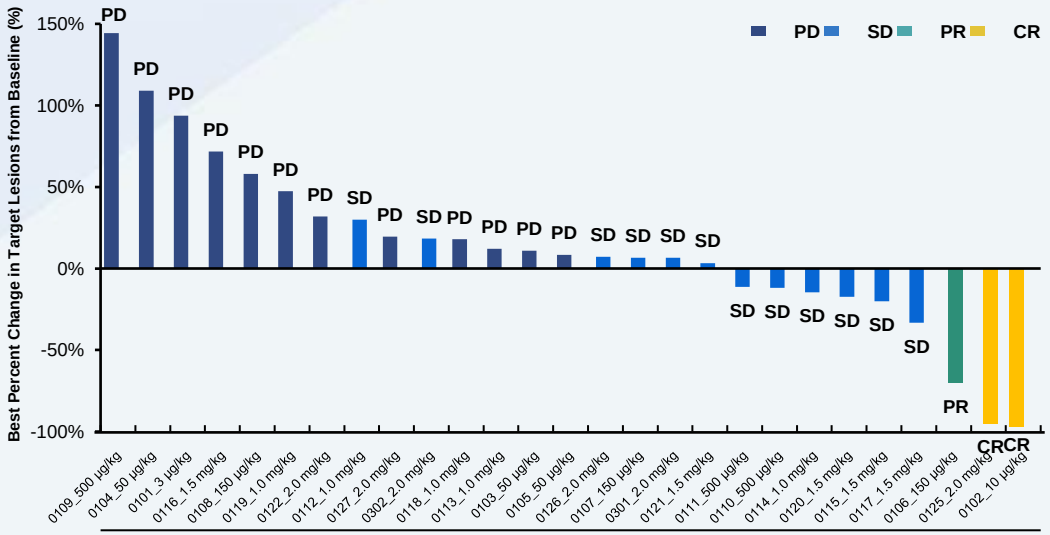
IMM01(timdarpacept)

Phase I Clinical Trial Results of IMM01 Monotherapy

One of the only two companies to have observed **CR in monotherapy** clinical trials with a **well tolerated safety profile**

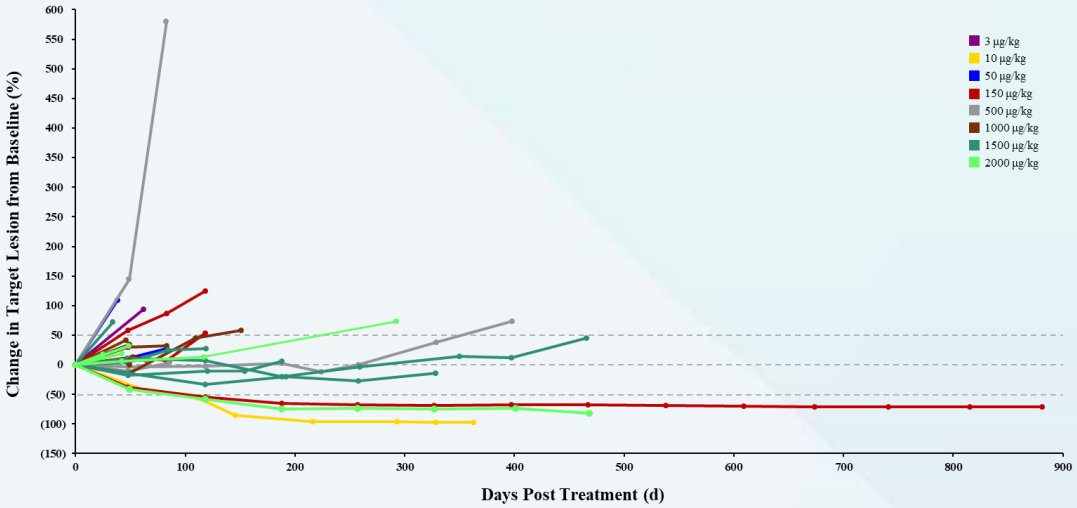
Potent Antitumor Activity and Encouraging Preliminary Clinical Efficacy

Response Observed in Patients Treated with IMM01 Monotherapy



Note: The colors of bars represent the best overall changes in size of target tumor lesions among 27 evaluable patients in the Phase I monotherapy study
Source: Company Data, as of December 14, 2022

Duration of Response in Patients Treated with IMM01 Monotherapy



Among 27 evaluable patients receiving **0.003 mg/kg** to **2.0 mg/kg** dosage, two patient reached complete response (**2 CRs**), one reached partial response (**1 PR**), and 13 reached stable disease (**13 SDs**) (including **six cases** with **observed substantial tumor shrinkage**)

Source: Company Data

IMM01(timdarpacept)

Phase I Clinical Trial Results of IMM01 Monotherapy

Safety Results

Majority of TRAE is **grade 1 and 2**

Grade 3 and above TRAE mainly include **Leukopenia, Thrombocytopenia, Anemia, Neutropenia**, with the highest rate of occurrence as **14% (4/29)**

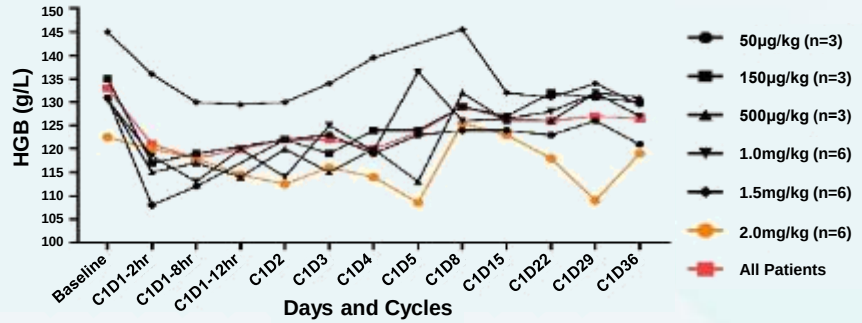
Treatment-related adverse event (n=29)	ALL n (%)	≥Gr 3 n (%)
Positive of Anti erythrocyte antibody	17 (59)	
Leukopenia	16 (55)	2 (7)
Hemolysis	15 (52)	
Infusion related reaction	15 (52)	
Thrombocytopenia	13 (45)	3 (10)
Hypertriglyceridemia	13 (45)	
Anemia	13 (45)	4 (14)
Neutropenia	12 (41)	1 (3)
Neutrocytosis	12 (41)	
Alkaline phosphatase increased	8 (28)	
Leukocytosis	8 (28)	
Hyperbilirubinemia	7 (24)	
Hypercholesteremia	6 (21)	
Fever	5 (17)	
Proteinuria	5 (17)	
ALT increased	4 (14)	
GGT increased	3 (10)	
Hyperuricemia	3 (10)	
Hypothyroidism	3 (10)	
AST increased	4 (14)	

Notes:
1. TRAE above 10% is presented
2. IMM01 is generally safe and well tolerated in 29 patients
3. Majority of TRAEs were grade 1 and 2
4. Grade 3 and above TRAEs mainly include Leukopenia, Thrombocytopenia, Anemia, Neutropenia, with the highest rate of occurrence as 14% (4/29)

Source: Company Data

The impact on hemoglobin or platelet is **transient and insignificant** following the administration of IMM01.

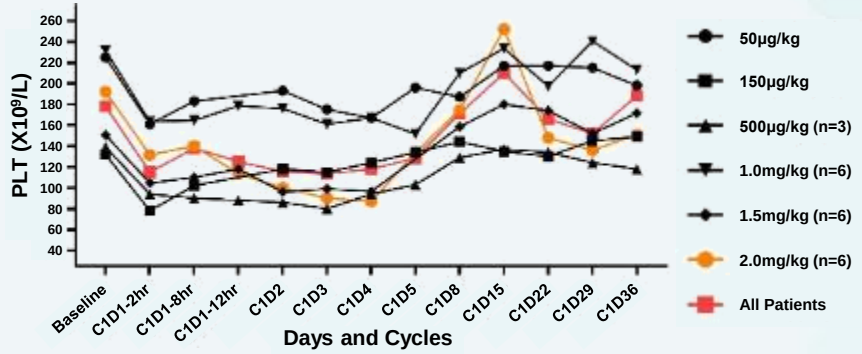
HGB Changes Following Single-dose and Cycle 1 by Cohort



Although a transient decrease of hemoglobin was observed at 8 to 24 hours after the first dosing, it would generally get back to normal level between day 2 and 4.

Note: Dosing days are C1D1, C1D8, C1D15, C1D22, C1D29, C1D36.

PLT Following Single-dose and Cycle 1 by Cohort



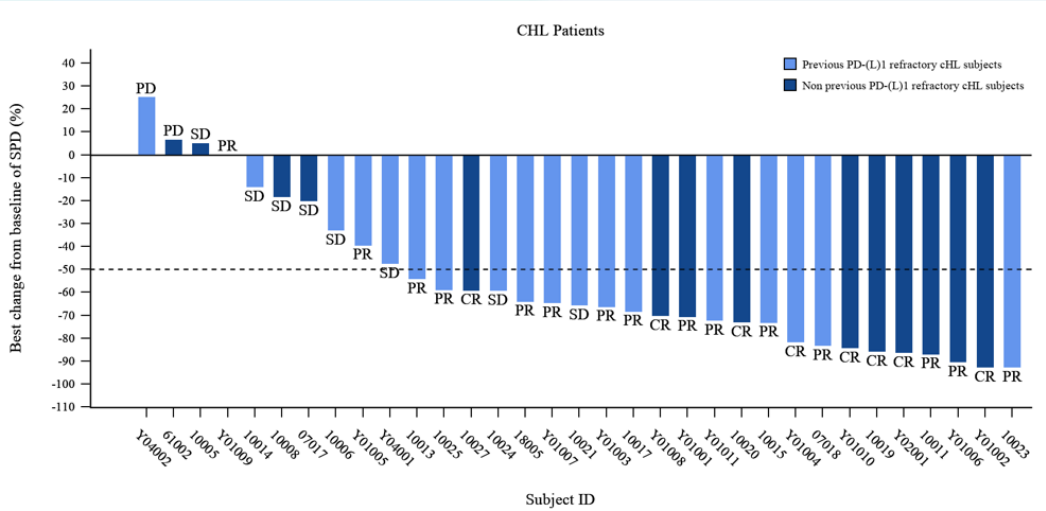
Transient decrease in platelet was also observed at 2 hours after the first dosing, but it generally returned to normal level after 5 days.

Note: Dosing days are C1D1, C1D8, C1D15, C1D22, C1D29, C1D36.

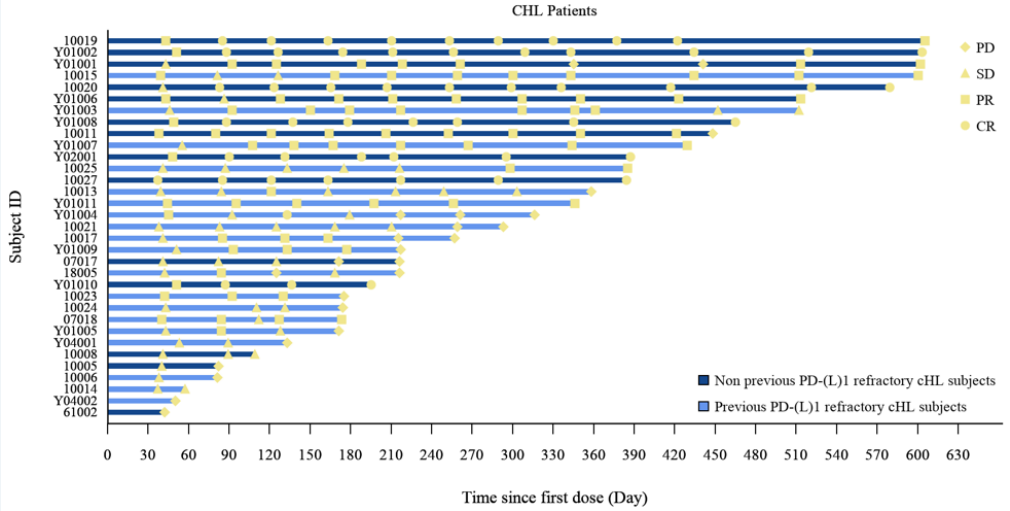
IMM01 (timdarpacept) + Tislelizumab (PD-1 mAb)

Phase II Efficacy in Prior Anti-PD-1 Failed R/R cHL

Best Percentage Change from Baseline in Target Lesion



Duration of Treatment and Response



Received approval from the NMPA for the protocol of the Phase III clinical trial of IMM01 in combination with tislelizumab versus physician's choice chemotherapy in prior PD-(L) 1-refractory cHL in April 2024. FPI reached in July 2024

2024 ASCO ANNUAL MEETING

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ASH

Oral Presentation

Best Overall Response n (%)	R/R cHL (N=33)
ORR	**23 (69.7)**
DCR	**31 (93.9)**
CR	**8 (24.2)**
PR	**15 (45.5)**
SD	8 (24.3)
PD	2 (6.1)

Source: Company Data; The clinical data is as of Dec 31st , 2024

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IMM01 (timdarpacept) + Tislelizumab (PD-1 mAb)

Phase II: Superior Efficacy in Anti-PD-1 Failed R/R cHL

	Timdarpacept (SIRPα-Fc) + Tislelizumab (PD-1)	Favezelimab (Anti-LAG-3) + Pembrolizumab [1]	Tifcemalimab (Anti-BTLA) + Toripalimab (PD-1) [2]
N	33	34	34
ORR	69.7%	29%	35.3%
CR	24.2%	9%	0%
Status	Phase III started in Jul 2024 to treat PD-(L)1 refractory cHL	Phase III of the coformulated two drugs started in Oct 2022 Stopped in Dec 2024	Phase III started in Dec 2023 to treat R/R cHL
Study Geography	China	China + International	China

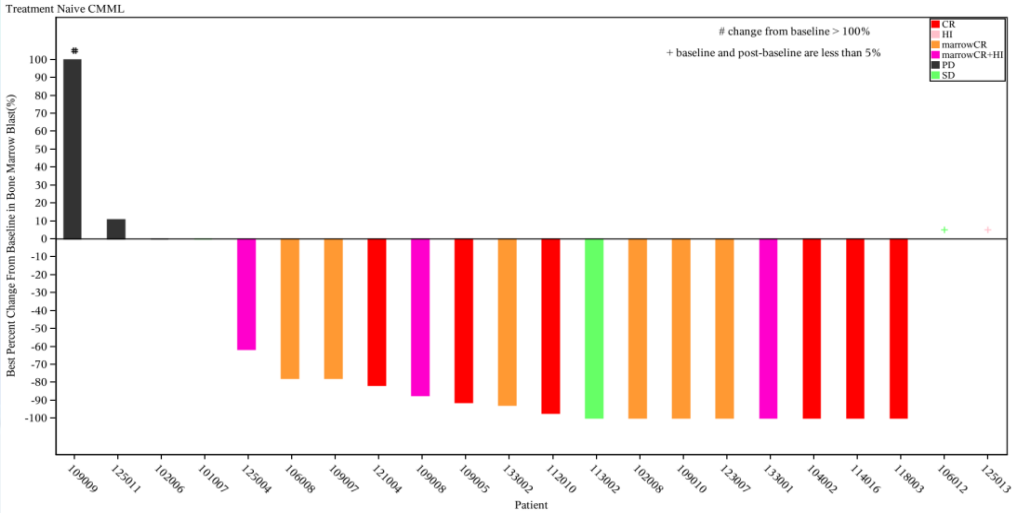
Source:

1. Timmerman et al. Blood (2022) 140 (Supplement 1): 768–770.
2. Song et al. Blood (2023) 142 (Supplement 1): 4458.Hodgkin Lymphoma. Histopathologically, 95% of HL cases are classified as cHL."- Momotow et al. J. Clin. Med. 2021, 10(5), 1125

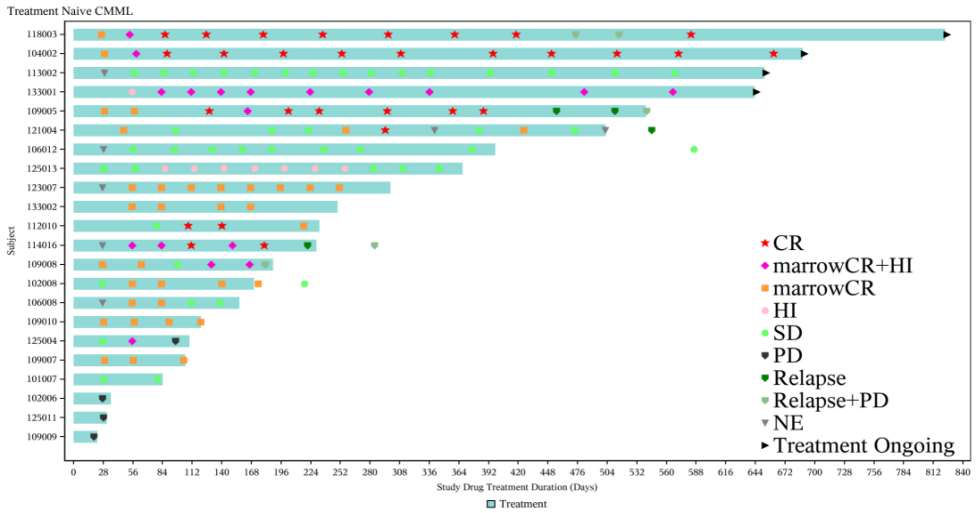
Company Data; The clinical data is as of Dec 31st , 2024

IMM01 (timdarpacept) + Azacitidine in 1L CMML (Phase II)

Best Percent Change from Baseline in the Blast Cells in the Bone Marrow



Duration of Treatment and Response



Phase III study of IMM01 (Timdarpacept) in combination with azacitidine in patients with newly diagnosed CMML was approved by NMPA in June 2024, FPI in November 2024

ESMO Oral Presentation

Best Overall Response, n (%)	1L CMML (N=22)	≥4 months (N=16)	≥6 months (N=13)
ORR	**16 (72.7%)**	**14 (87.5%)**	**11 (84.6%)**
CR	**6 (27.3%)**	**6 (37.5%)**	**6 (46.2%)**
mCR + HI	3 (13.6%)	2 (12.5%)	2 (15.4%)
mCR alone	6 (27.3%)	5 (31.3%)	2 (15.4%)
HI	1 (4.5%)	1 (6.3%)	1 (7.7%)

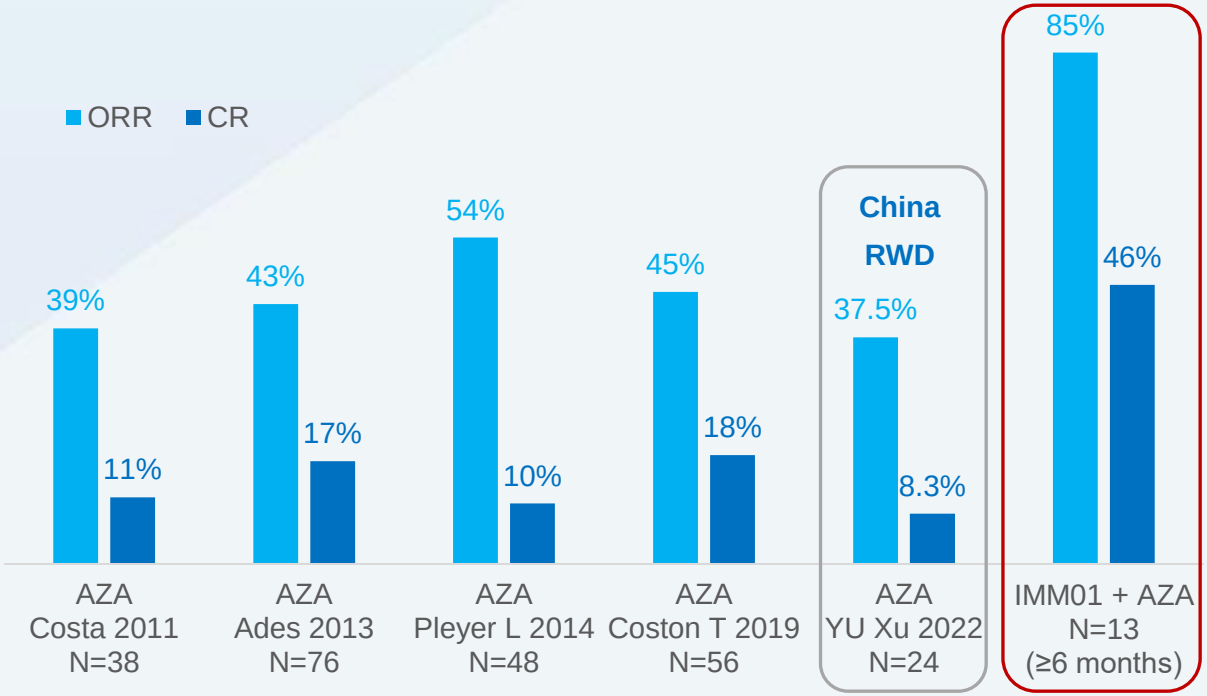
Notes: ORR = Overall Response Rate, CR = Complete Response, mCR = Marrow Complete Response, HI = Hematological Improvement

Source: Company Data; The clinical data is as of Dec 31st, 2024

IMM01 (timdarpacept) + Azacitidine in 1L CMML

Comparison in Treating 1L CMML

Response of Major Clinical Studies in CMML



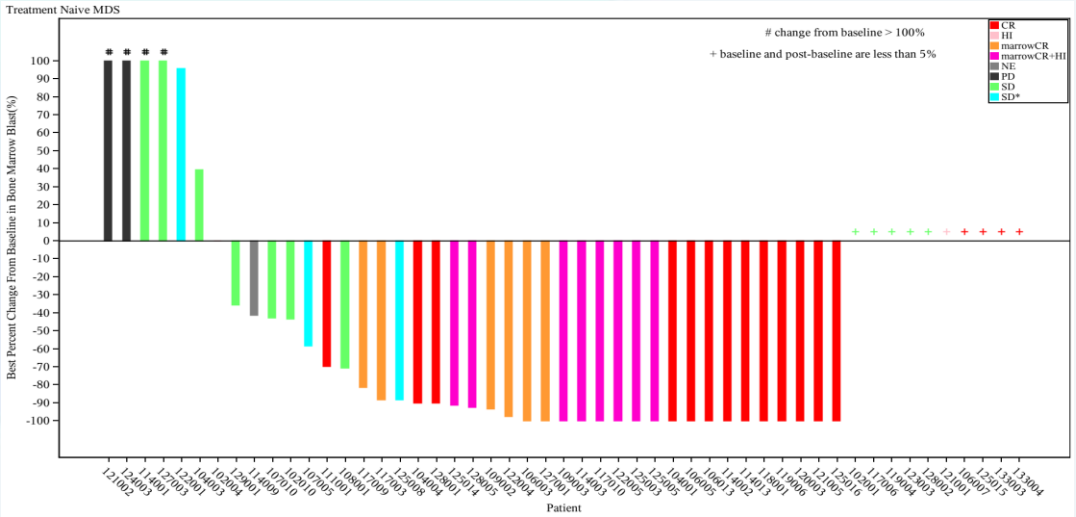
- As indicated by the graph, the ORR and CR rates range from 37% to 54% and 8% to 18% respectively in major clinical trials of azacitidine in CMML based on historical data.
- Particularly, real-world data on efficacy and safety of azacitidine therapy in 24 patients with CMML from a multicenter, retrospective study in **China** published in July 2022 **showed an ORR of 37.5% with a CR rate and a mCR/HI rate of 8.3% and 20.8%, respectively**. In contrast, in our Phase II trial for the combination of IMM01 and azacitidine, among the 13 evaluable patients (≥6 months) with 1L CMML, six reached complete response (**6 CRs**), four reached marrow complete response with two hematological improvement (**2 mCRs + HI and 2 mCRs alone**), and one reached hematological improvement alone (**1 HI alone**), **resulting in an ORR of 84.6% and a CR rate of 46.2%**.

Notes:
1. ORR refers to overall response rate; CR refers to complete response.
2. There were no head-to-head comparison clinical trials conducted between these drugs. The results of clinical trials of a drug cannot be directly compared to that of another drug and may not be representative of the overall data.

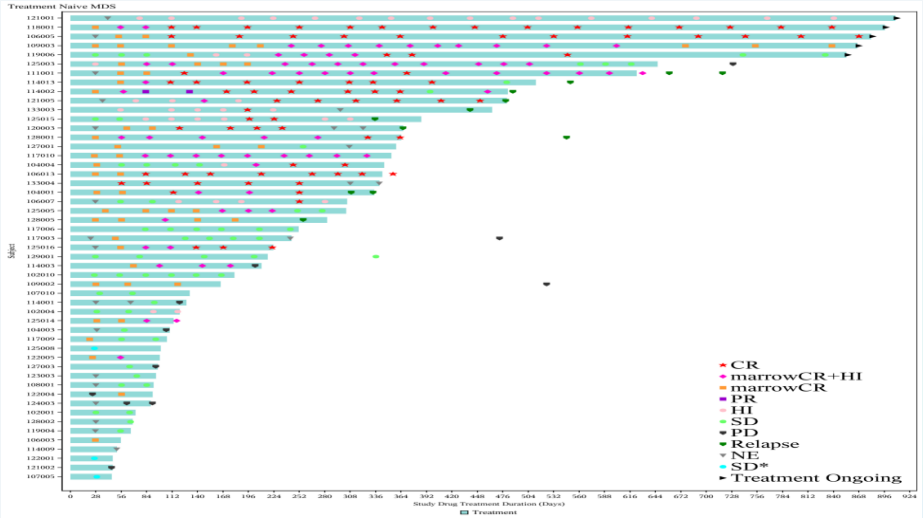
Source: Literature Review; Company Data, the clinical data is as of Dec 31st, 2024

IMM01 (timdarpacept) + Azacitidine in 1L MDS (Phase II)

Best Percentage Change from Baseline in the Blast Cells in the Bone Marrow (%)



Duration of Treatment and Response



Phase III study of IMM01 in combination with azacitidine in patients with newly diagnosed higher-risk MDS was approved by NMPA in May 2024

2024 ASCO ANNUAL MEETING

ASH

Oral Presentation

Best Overall Response n (%)	1L MDS (N=51)	≥4 months (N=34)	≥6 months (N=29)
ORR	**33 (64.7%)**	**29 (85.3%)**	**26 (89.7%)**
DCR	**45 (88.2%)**	**34 (100%)**	**29 (100%)**
CR	**17 (33.3%)**	**17 (50.0%)**	**17 (58.6%)**
mCR+HI	8 (15.7%)	7 (20.6%)	6 (20.7%)
mCR alone	6 (11.8%)	3 (8.8%)	2 (6.9%)
HI	2 (3.9%)	2 (5.9%)	1 (3.4%)
SD	12 (23.5%)	5 (14.7%)	3 (10.3%)

Notes: ORR = Overall Response Rate, CR = Complete Response, mCR = Marrow Complete Response, HI = Hematological Improvement, SD = Stable Disease

Source: Company Data; The clinical data is as of Dec 31st, 2024

IMM01 (timdarpacept) + Azacitidine

Comparison: Safety results

Magrolimab + AZA vs AZA alone

	MDS Ib Magrolimab + AZA (N=95)		AZA-001 MRCT AZA alone (N=175)	
TRAE	**All grades, N(%)**	**≥Grade 3, N(%)**	**All grades, N(%)**	**≥Grade 3, N(%)**
Anemia	49 (51.6%)	**45 (47.4%)**	90 (51.4%)	**24 (13.7%)**
Leukopenia	**28 (29.5%)**	**28 (29.5%)**	**32 (18.2%)**	**26 (14.9%)**
Neutropenia	45 (47.4%)	44 (46.3%)	115 (65.7%)	107 (61.1%)
Febrile neutropenia	**29 (30.5%)**	**27 (28.4%)**	**24 (13.7%)**	**22 (12.6%)**
Thrombocytopenia	52 (54.7%)	44 (46.3%)	122 (69.7%)	102 (58.3%)

Compared to the trial of AZA alone, **significant higher rates of occurrence of some TRAEs** (such as anemia, leukopenia and febrile neutropenia) were observed in the clinical trial for the combination of Magrolimab and AZA.

IMM01 + AZA vs AZA alone

	IMM01-02 Study – MDS Cohort IMM01 + AZA (N=57)		China MDS-002 Single-arm Study AZA alone (N=72)	
TRAE	**All grades, N(%)**	**≥Grade 3, N(%)**	**All grades, N(%)**	**≥Grade 3, N(%)**
Anemia	27 (47.4%)	25 (43.9%)	38 (52.8%)	35 (48.6%)
Neutropenia	38 (66.7%)	38 (66.7%)	48 (66.7%)	48 (66.7%)
Thrombocytopenia	41 (71.9%)	38 (66.7%)	52 (72.2%)	50 (69.4%)

Compared to the trial of AZA alone, **similar rates of occurrence of TRAEs** were observed in our phase II trial for the combination of IMM01 and AZA.

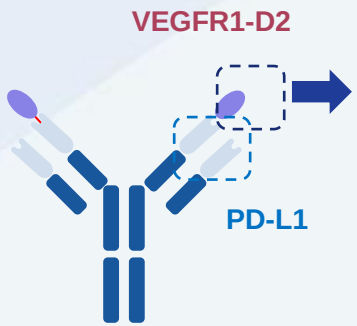
Source: Valeria Santini1 et al, Eur J Haematol. 2010 August ; 85(2): 130–138.
David et al. A.J Clin Oncol ,2023,41:2815-2826;
Company Data; The clinical data is as of Dec 31st, 2024

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

A bsAb with the mAb-Trap Structure Targeting VEGF and PD-L1

IMM2510 - Target Introduction and Molecule Structure

IMM2510 Molecule Structure



VEGF

VEGF receptor trap binds multiple VEGF receptor ligands beyond VEGF-A for broader antiangiogenic activity

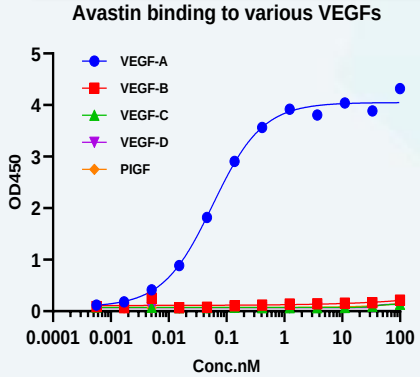
PD-L1

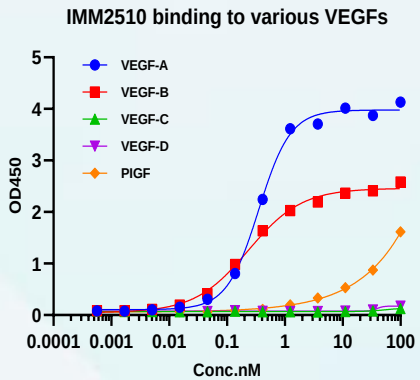
Tumor cells expressing PD-L1 can **bind to PD-1** on the surface of T cells to evade T-cell attacks

ADCC

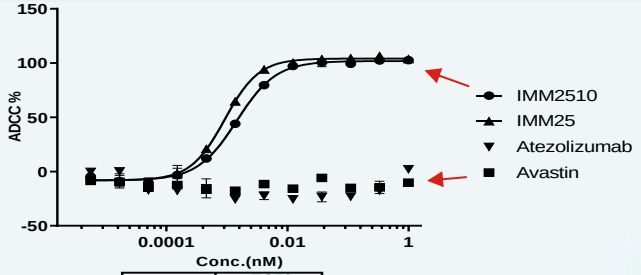
ADCC-enhanced antibody designed to induce direct killing of immunesuppressive PD-L1+ tumor cells

IMM2510 binds multiple VEGF receptor ligands





IMM2510 has enhanced ADCC activity



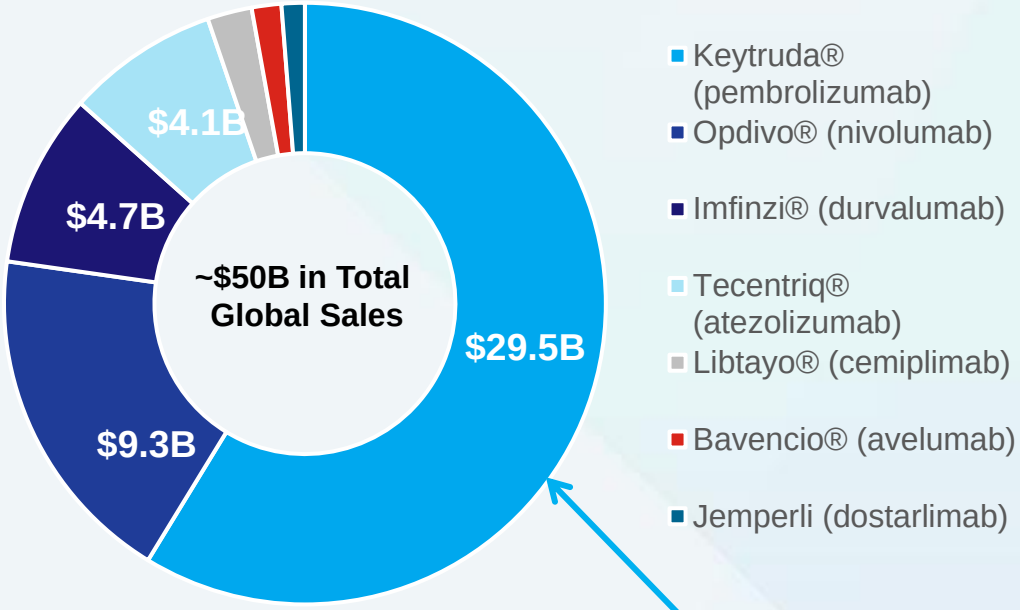
	EC50
IMM2510	0.001461
IMM25	0.0009247

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

IMM2510 targets largest market in oncology: NSCLC

- **NSCLC is the largest market opportunity for Keytruda,** accounting for ~ 1/3 of sales
- **PD-(L)1** inhibitors are estimated to reach ~$90B in global sales in 2028[1]
  - Four PD-(L)1 inhibitors achieved >$4B in sales in 2024[2]
- **VEGF** inhibitor market represents additional opportunity for expansion

2024 Sales of PD-(L)1 Inhibitors[2]



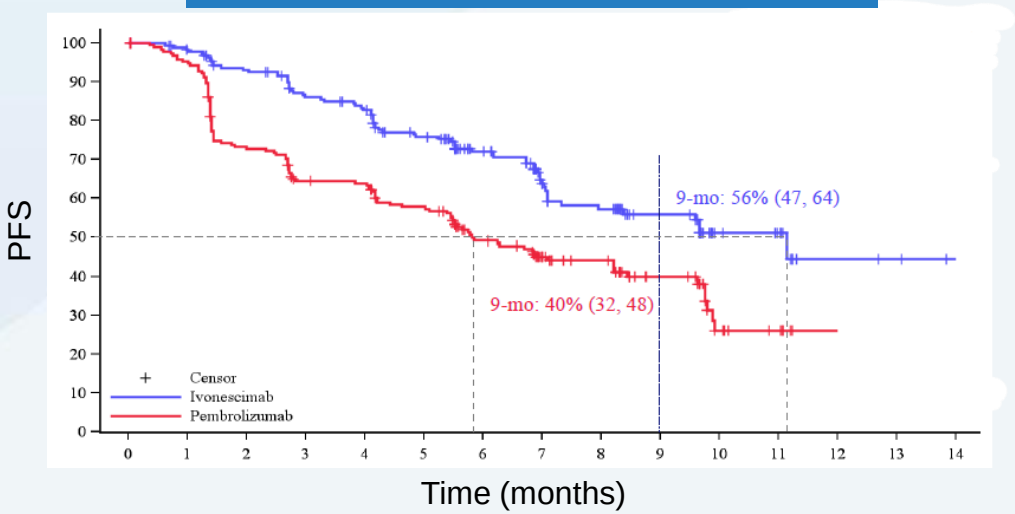
Keytruda® (pembrolizumab) alone represented **$29.5B**, with ~**$10B** coming from lung cancer indications.[3]

[1] IQVIA Institute for Human Data Science, "Global Oncology Trends 2024: Outlook to 2028"
[2] Company earnings releases
[3] Stifel research report published on March 25, 2024.

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

PD-(L)1xVEGF Bispecifics Outperform Pembrolizumab

Ivonescimab: HARMONi-2 Trial[1]



In the Phase III HARMONi-2 trial, ivonescimab **showed clinically meaningful improvement over pembrolizumab** in patients with PD-L1-positive NSCLC on PFS (HR:0.51, p<0.0001) and OS (HR:0.777, p=NS).

PD-(L)1xVEGF bispecifics have largely avoided significant VEGF-associated toxicities, including serious bleeding events.

BNT327: TNBC Trial[2]

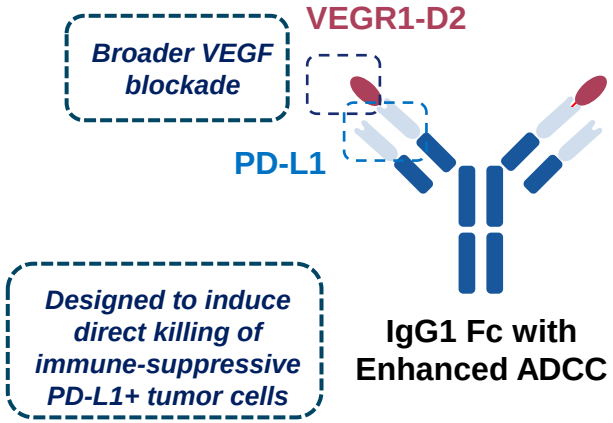
BNT327 drove clinical benefit irrespective of PD-L1 status in combination with chemotherapy in patients with TNBC, demonstrating that PD-(L)1xVEGF bispecifics **can potentially treat patient populations not currently addressed by existing PD-(L)1 therapies**.

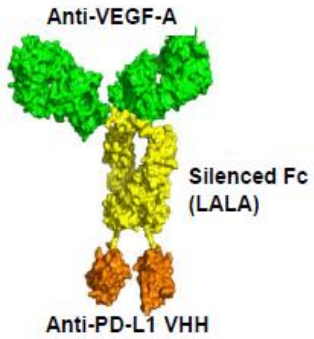
[1] Zhou et al. Presented at WCLC 2024.
[2] Y. Meng et al. Presented at ESMO 2024.
NS = not statistically significant; TNBC: triple-negative breast cancer

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

Key Competitor Landscape

	IMM2510 (ImmuneOnco / Instil Bio)	PM8002 (BioNTech)	AK112 (Akeso / Summit)
VEGF binding	VEGF-A, VEGF-B, PlGF	VEGF-A	VEGF-A
PD-1 or PD-L1	PD-L1	PD-L1	PD-1
ADCC	Enhanced ADCC	None	None

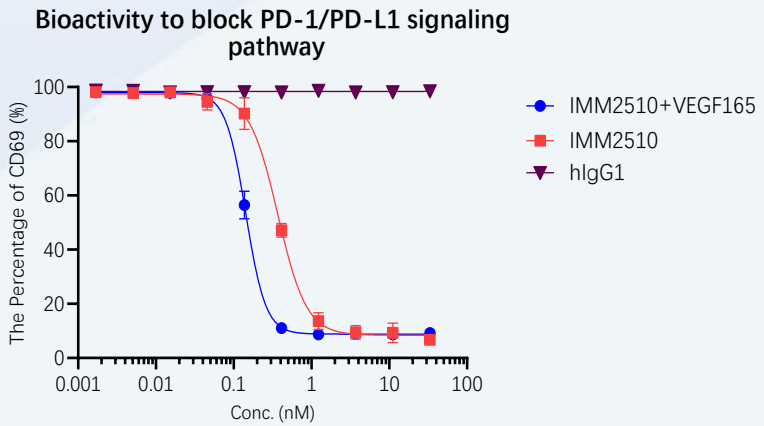




IMM2510 (palverafusp alfa) (VEGF × PD-L1)

IMM2510 demonstrates cooperative binding to PD-L1 *in vitro*

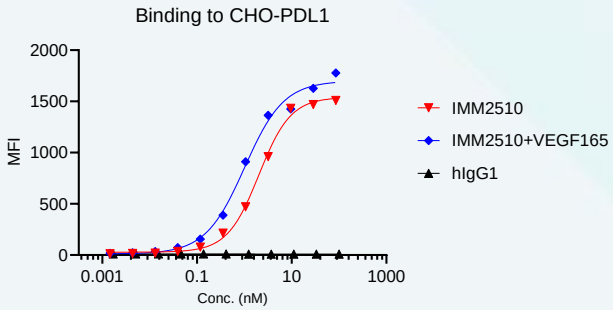
Presence of VEGF enhances PD-1 signaling inhibition by IMM2510



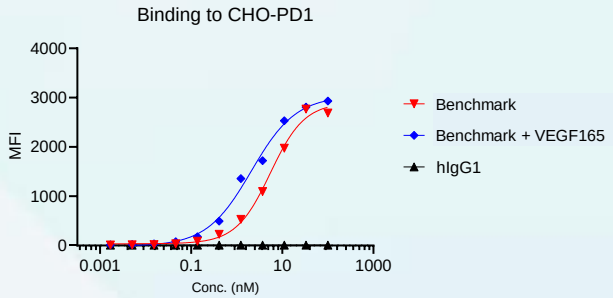
	IMM2510	IMM2510+VEGF165
IC50	0.3697	0.1429

- IMM2510 demonstrates enhanced blockade of PD-1/PD-L1 signaling in the presence of VEGF (cooperative effect)

Binding of IMM2510 and benchmark antibody to CHO-PDL1 and CHO-PD1 cells, respectively, is enhanced with VEGF



	IC50
IMM2510	2.035
IMM2510+VEGF165	1.013



	IC50
Benchmark	5.464
Benchmark +VEGF165	2.094

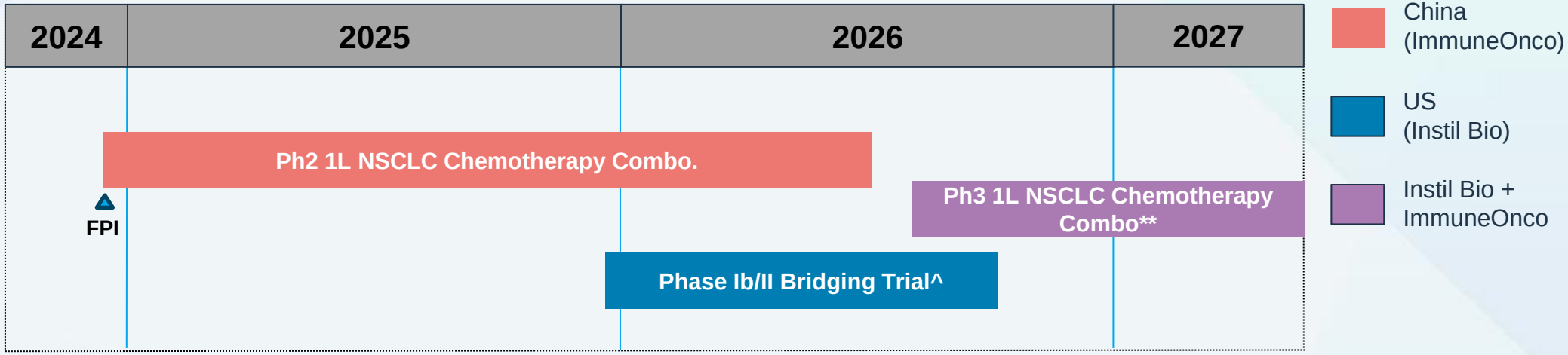
- Competitor benchmark antibody* and IMM2510 demonstrate similar shift in binding affinity to PD-1 and PD-L1, respectively, in the presence of VEGF

*Competitor benchmark antibody from most clinically advanced PD1xVEGF bispecific program

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

IMM2510 development strategy prioritizes 1L NSCLC

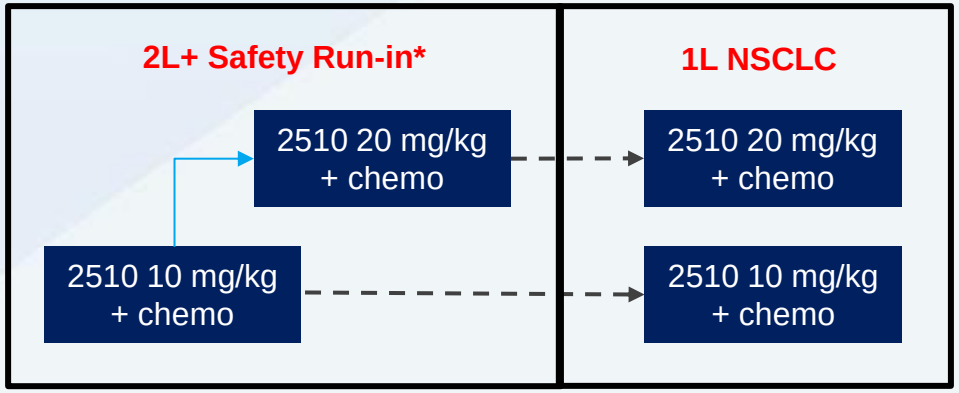
- Opportunity to be best-in-class with differentiated molecular structure: VEGF trap and ADCC-enhancement
- **IMM2510 + chemo Phase II in 1L NSCLC** is ongoing in China
- US-based Phase Ib/II bridging trial initiation anticipated before year-end 2025, assuming necessary regulatory approvals
- US Clinical development plan takes advantage of rapid enrollment in China
  - >190*patients dosed to date in multiple solid tumors



*As of May 21, 2025 data cut
**Subject to regulatory discussions
^Anticipated to start as solid tumor dose optimization in monotherapy enriching for NSCLC with or without chemotherapy

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

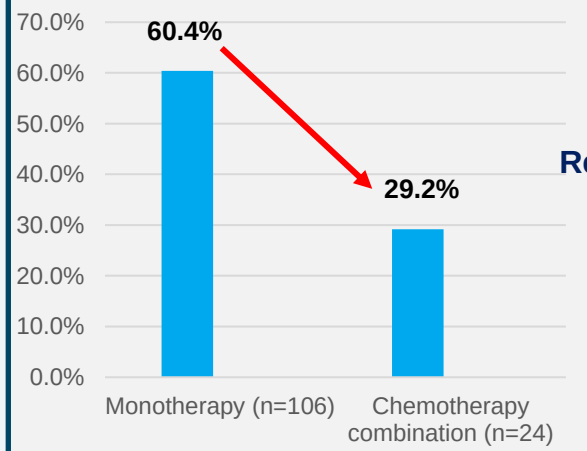
Phase Ib/II trial of IMM2510 + chemo in 1L NSCLC



Enrollment Update**

- **1L NSCLC:** >20 pts enrolled
- **2L+ NSCLC safety run-in:** 12 patients enrolled
- ImmuneOnco may provide an update on **initial safety and efficacy results in >60 1L pts in 2H 2025**

Safety Update***



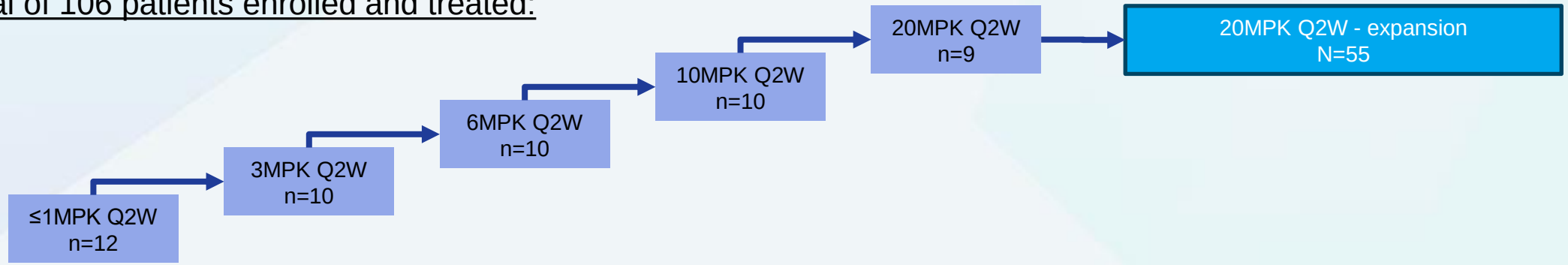
Reduced frequency and severity of IRRs in chemotherapy combination study

*Safety run-in patients are patients with relapsed/refractory NSCLC
**As of May 21,2025 | ***As of May 9, 2025; preliminary data
Histology-based platinum doublet chemotherapy; chemo used for 4 cycles. IMM2510 is given in a Q3W schedule.

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

Phase I/II monotherapy trial baseline characteristics

Total of 106 patients enrolled and treated:



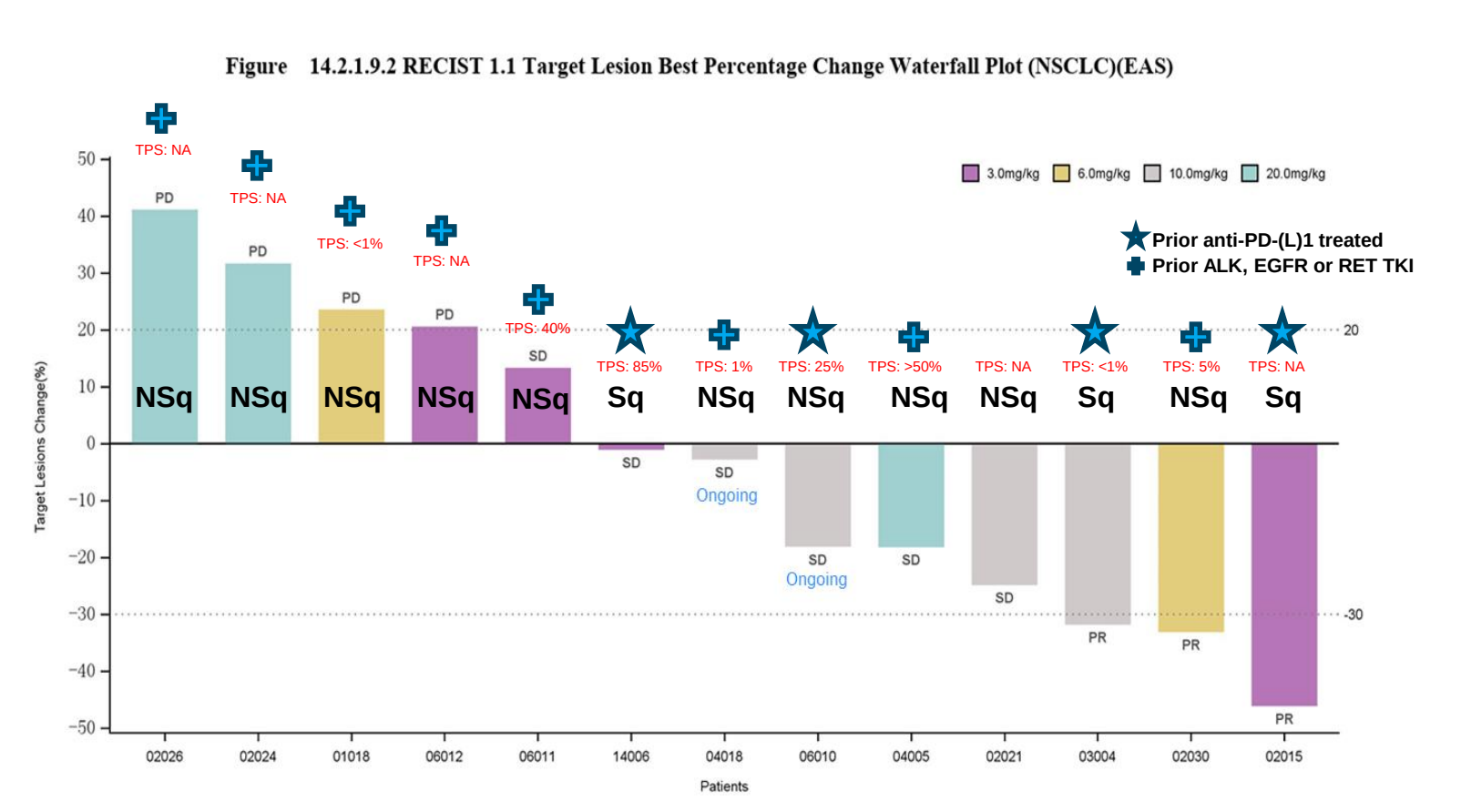
Baseline characteristics	Dose escalation; n=51	Dose expansion; n=55
Age: median (min – max)	58 (36 – 75)	47 (22 – 49)
Race	Asian 100%	Asian 100%
Gender: M / F (%)	43% / 57%	46% / 55%
ECOG 0/1 (%)	8% / 92%	9% / 91%
# of prior lines of therapies: median (min – max)	3 (1 - 13)	2 (0 – 12)
Main indications	NSCLC: 35.3% Breast cancer: 15.7% (mostly non-TNBC)	Soft tissue Sarcoma: 41.8% TNBC: 18% HCC: 12.7%

* Data cut off date Dec 24, 2024. Study is ongoing, data subject to change.

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

13 efficacy evaluable NSCLC patients
Late-line, heavily pretreated patients (squamous and non-squamous)

- 23.1% ORR
- 62% of patients with tumor shrinkage
- Responses in patients with low (≤ 5%) PD-L1 TPS score and/or previously treated with checkpoint inhibitors



Data cut off date Dec 24, 2024. Study is ongoing, data subject to change.
TPS = Tumor Proportion Score | ORR = Objective response rate

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

Comparison of phase I/II NSCLC monotherapy activity

BNT327 NSCLC 2L+ monotherapy (ASCO 2024)

Efficacy

Cohort 2 (36 evaluable patients)

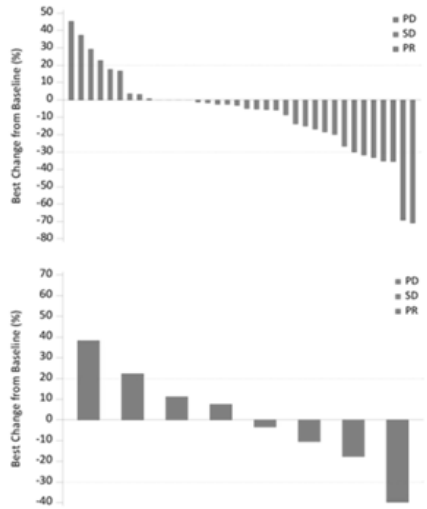
- ORR was 19.4% with a DCR of 69.4%. mPFS was 5.5 months (Table 3).

Cohort 3 (8 evaluable patients)

- ORR was 12.5% with a DCR of 62.5%. mPFS was 6.7 months (Table 3).

EGFRm NSCLC who failed prior TKI

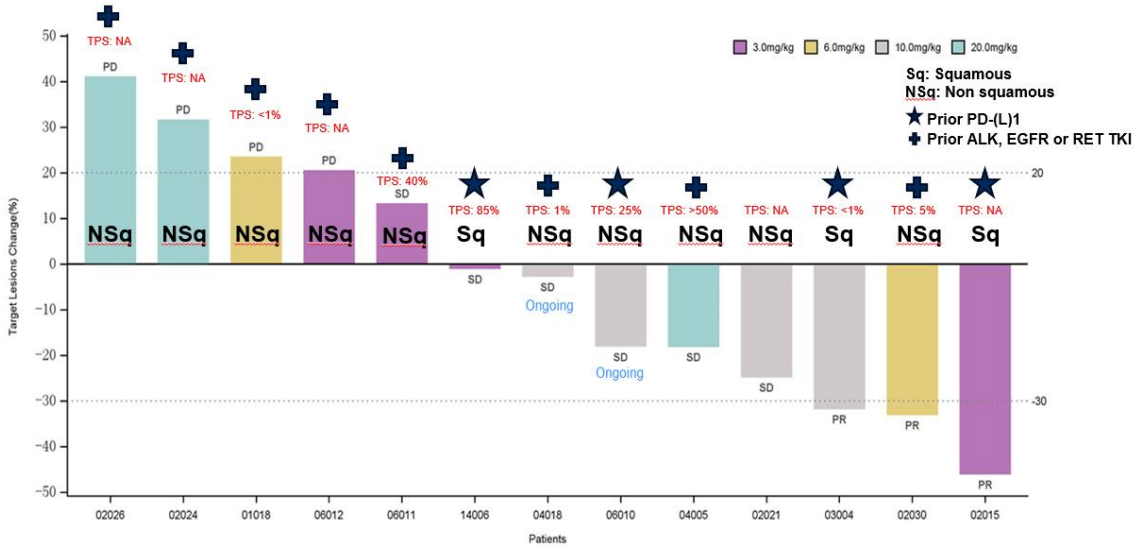
EGFR/ALK wt who failed PD-1/L1 and platinum-based chemo



IMM2510 NSCLC 2L+ monotherapy

13 evaluable pts: **ORR = 23.1%**; DCR = 69.2%

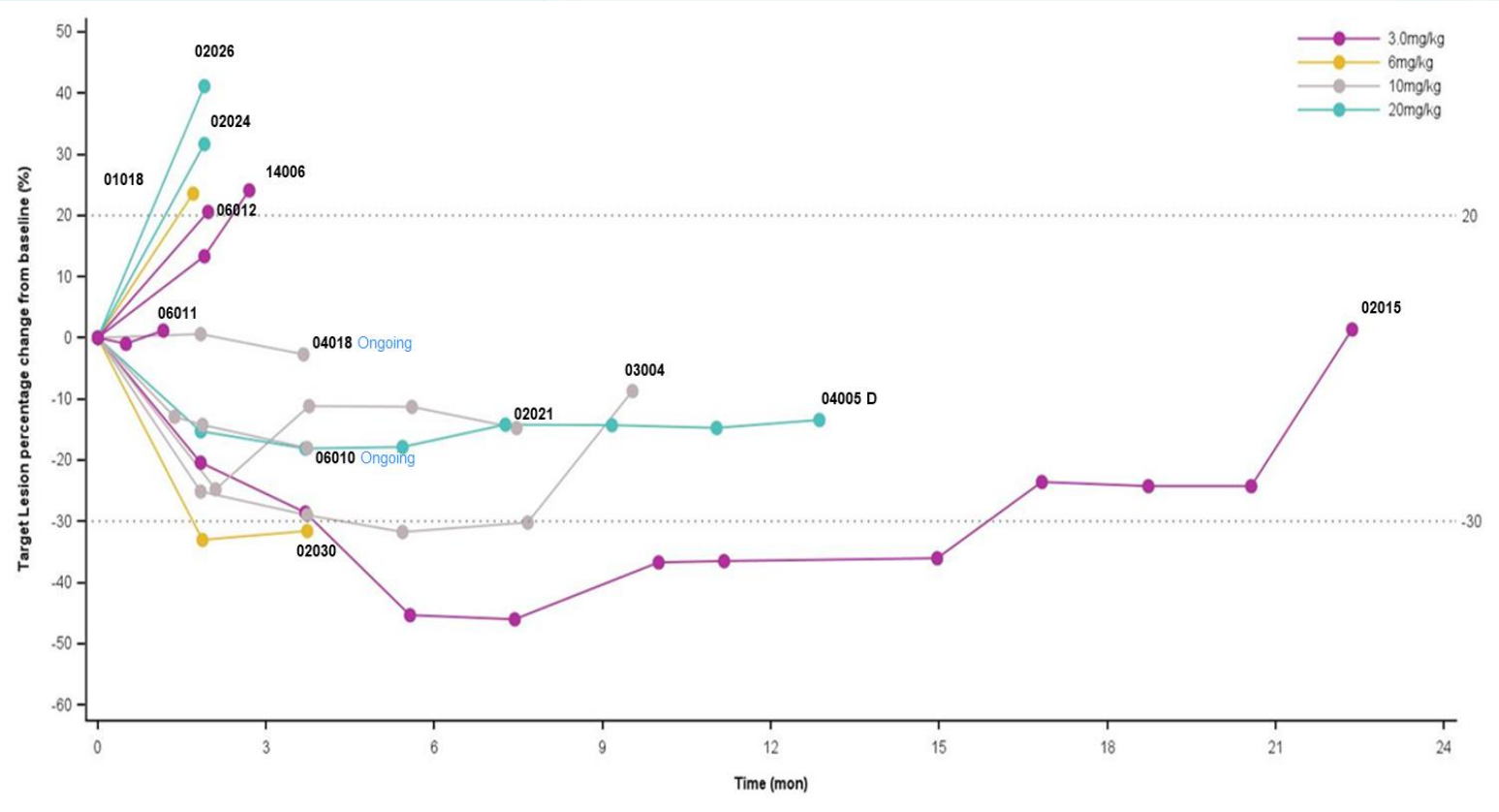
Figure 14.2.1.9.2 RECIST 1.1 Target Lesion Best Percentage Change Waterfall Plot (NSCLC)(EAS)



Source: Wu et al, ASCO 2024; Not from head-to-head trials. Differences in populations make cross-trial comparisons inherently limited.
ORR = Objective response rate | DCR = Disease control rate

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

13 efficacy evaluable NSCLC pts treated with monotherapy IMM2510, several patients with prolonged benefit



Data cut-off date Dec 24, 2024; studies ongoing, data subject to change

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IMM2510 (palverafusp alfa) (VEGF × PD-L1)

IMM2510 Compares Favorably to Competitor Monotherapy Phase I Datasets in NSCLC

	IMM2510[1]	Ivonescimab[2]	BNT327[3]	BNT327[3]
Population	All-comers	EGFR/ALK/ROS wild-type	EGFR mutant	EGFR/ALK wild-type
Indication	NSCLC	NSCLC	NSCLC	NSCLC
Dose	3-20 mg/kg Q2W	10-30 mg/kg Q2/3W	20 mg/kg Q2W	20 mg/kg Q2W
n (eff. eval.)	13	15	36	8
# Prior Lines	1 or more **Median 3L**	**1**	1 or more	1 or more
Prior anti-PD-1 (if applicable)	YES	**NO***	N/A	YES
ORR	**23%**	**33%**	**19%**	**13%**

Similar ORR in more challenging patient population vs ivonescimab
Similar ORR in similar patient population vs BNT327

Not from head-to-head trials. Differences in populations make cross-trial comparisons inherently limited.
Sources: [1] Data cut off date Dec 24, 2024. Study is ongoing, data subject to change. [2] Wang et al, J Thor Onc 2024 (Supplementary Table S6; Second-line only); [3] Wu et al ASCO 2024
*One patient had previously failed a PD-1xCTLA-4 bispecific plus platinum-based chemotherapy.

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IMM2510 (palverafusp alfa) (VEGF × PD-L1)

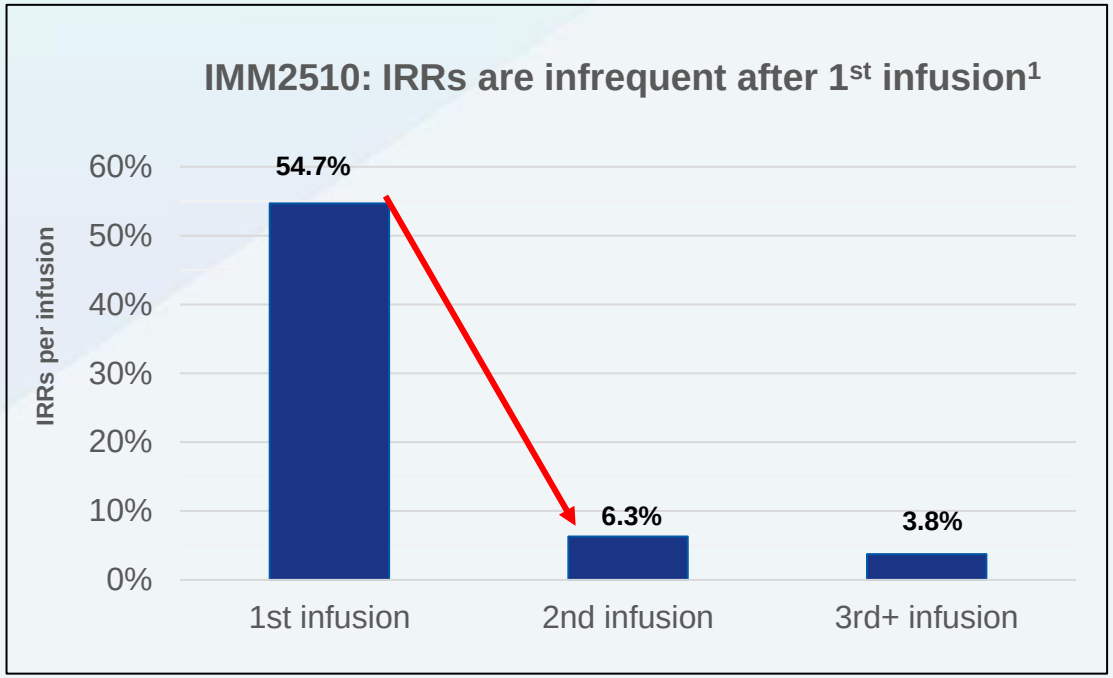
‘IMM2510 safety comparable to other PD-(L)1xVEGF bispecifics

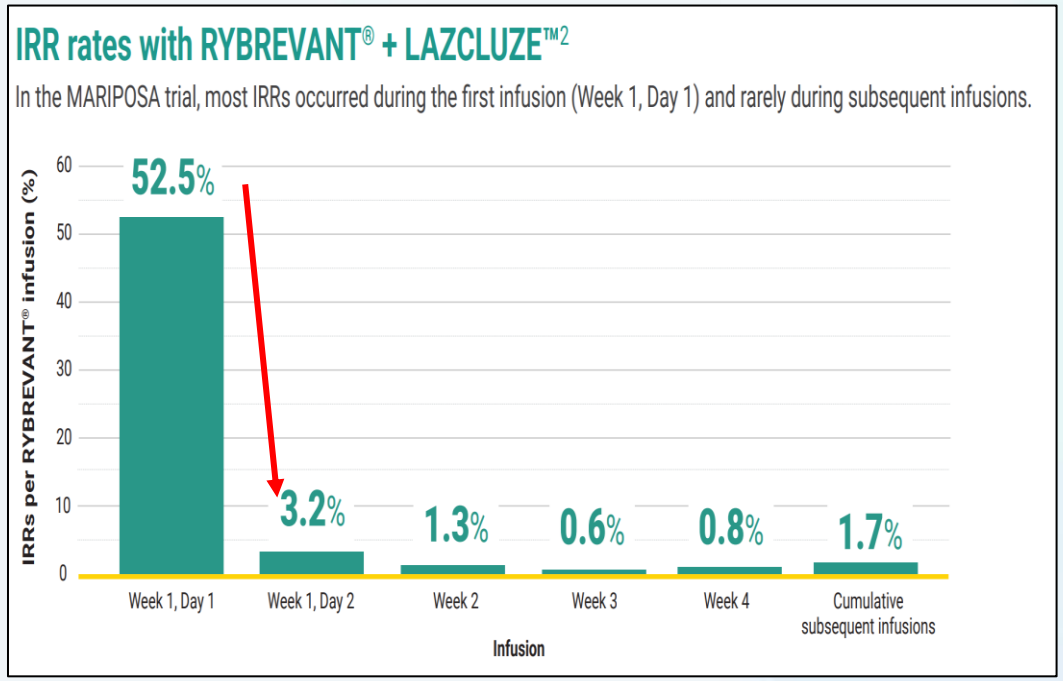
Category	Ivonescimab Phase Ia (n=51)[1]	BNT327 Phase Ia (n=80) [2]	IMM2510 Phase I[3] (n=106)
TRAEs	74.5%	77.5%	94.3%
TRAEs grade 3	27.5%	22.5%	21.7%
Serious TRAEs	5.9%	N/R	12.3%
TRAEs leading to discontinuation	7.8%	10%	4.7%
TRAEs leading to death	0%	N/R	0.9%*
Infusion-related reactions**	7.8%	NR	60.4%
Grade 3+	*0%*	*NR*	*3.8%*
Grade 3+ immune-related	N/R	0%	3.8%
Possible VEGF–related (Grade 3+)			
Hypertension (Grade 3+)	*13.7%*	*6.3%*	*0.9%*
Proteinuria (Grade 3+)	*0.9%*	*0%*	*0%*

*One patient died due to an event of hypersensitivity (not reported as IRR) at 20mg/kg.
**Potentially indicative of active ADCC, a differentiated mechanism
Sources: [1] Frentzas et al, JITC 2024; [2] Guo et al, SITC 2022; [3] Data cut off date Dec 24, 2024. Study is ongoing, data subject to change.

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

IMM2510 IRRs Are Generally Limited to 1st Infusion





- IRRs are not uncommon with infusions of Fc-active antibodies or bispecifics.
- As with the RYBREVANT® + LACLUZE™ experience, rates of IRRs decrease considerably after the initial infusion for IMM2510.

[1] ImmuneOnco internal data on file, n=106.
[2] RYBREVANT® + LAZCLUZE™: Infusion-related Reactions (IRRs) Monitoring and Management

宜明昂科 ImmuneOnco

IMM2510 (palverafusp alfa) (VEGF × PD-L1)

Global Collaboration

On August 1, 2024, we reached a license and collaboration agreement with Axion Bio, Inc. (a wholly-owned subsidiary of Instil Bio (TIL US)) (formerly known as SynBioTx Inc.), pursuant to which Axion will in-license the global rights (outside the Greater China region) to our proprietary PD-L1xVEGF bispecific molecule IMM2510, as well as our next-generation anti-CTLA-4 antibody (ADCC+) IMM27M.

We will receive an upfront payment and potential near-term payments of up to **US$50 million** as well as potential additional development, regulatory, and commercial milestones payments of up to **US$2.1 billion,** plus single digit to low double-digit percentage royalties on global (outside the Greater China region) net sales.

We have received **US$20 million** as of 22 May, 2025

InstilBio

Developing One Owned Patent Family

- *1* issued patent in each of the U.S. and Japan; *1* issued patent in the PRC
- *1* pending patent application in each of Europe and the U.S.

Synergistic effect validated by approved anti-PD-(L)1 and anti-VEGF combo

	PD-L1	VEGF	PD-(L)1 Combo[1]
Molecule	TECENTRIQ, BAVENCIO, IMFINZI	AVASTIN	
IL Treatment	UC, SCLC, NSCLC	CRC, NSCLC	**RCC, HCC, NSCLC**
Others	NSCLC, HNSCC, Melanoma HCC, RCC, UC, HL	GBM, CRC, NSCLC, RCC, OC, CC	**EAC, CC**

宜明昂科 ImmuneOnco

IMM27M (tazlestobart) (CTLA-4 ADCC+)

A CTLA-4 mAb with Enhanced ADCC Activity

IMM27M - Mechanism of Action and Limitations of Approved Molecule

IMM27M Molecule Structure

Engineered IgG1 CTLA-4 mAb with Enhanced ADCC

- **Blocking the interaction** between CTLA-4 and CD80/CD86, and thus enhancing immune responses of T cells to tumor antigens
- Inducing enhanced immune responses targeting CTLA-4 **overexpressed T_{reg} cells**
- Promoting **T_{reg} depletion**, thus improving T-cell antitumor response to kill tumor cells

Currently Approved CTLA-4 Antibody with Unmodified Fc:

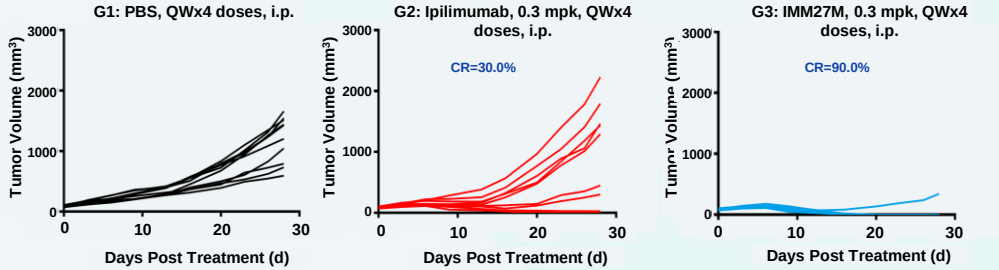
Limited efficacy → High dosage to achieve desirable efficacy → **Serious safety issues**

Clinical Development Plan

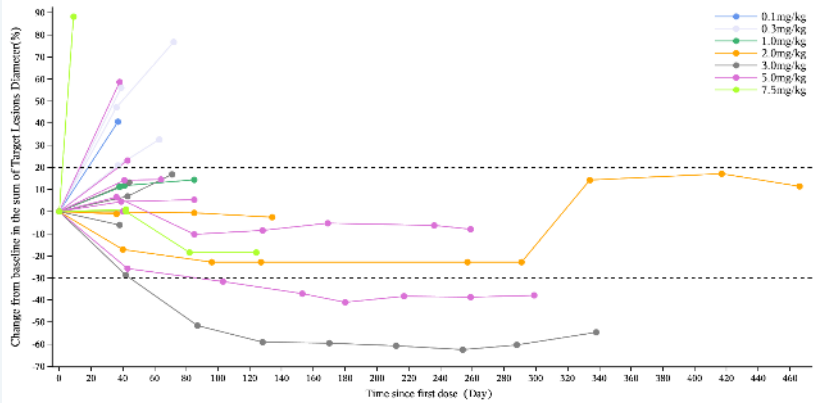
Jun 2022	*Mar 2023*	*Sept 2023*	*July 2024*
Phase I mono	IMM27M+PD-1 (advanced solid tumors) IND approval for Ph Ib/II	Phase I mono completed and confirmed RP2D	IMM2510 + IMM27M FPI

Stronger In Vivo Antitumor Effects and Preliminary Ph1 data

Efficacy Study in Colon Cancer (MC38) Syngeneic Mouse Model



Duration of Treatment and Best Response in Phase I



Preliminary efficacy:

2 confirmed PR and 3 SD with tumor shrinkage

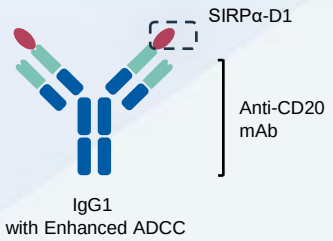
Source: Company Data; The clinical data is as of Dec 31st, 2024

IMM0306 (amulirafusp alfa) (CD47×CD20)

1st CD47 and CD20 Dual-targeting Bispecific to Enter into the Clinical Stage Globally

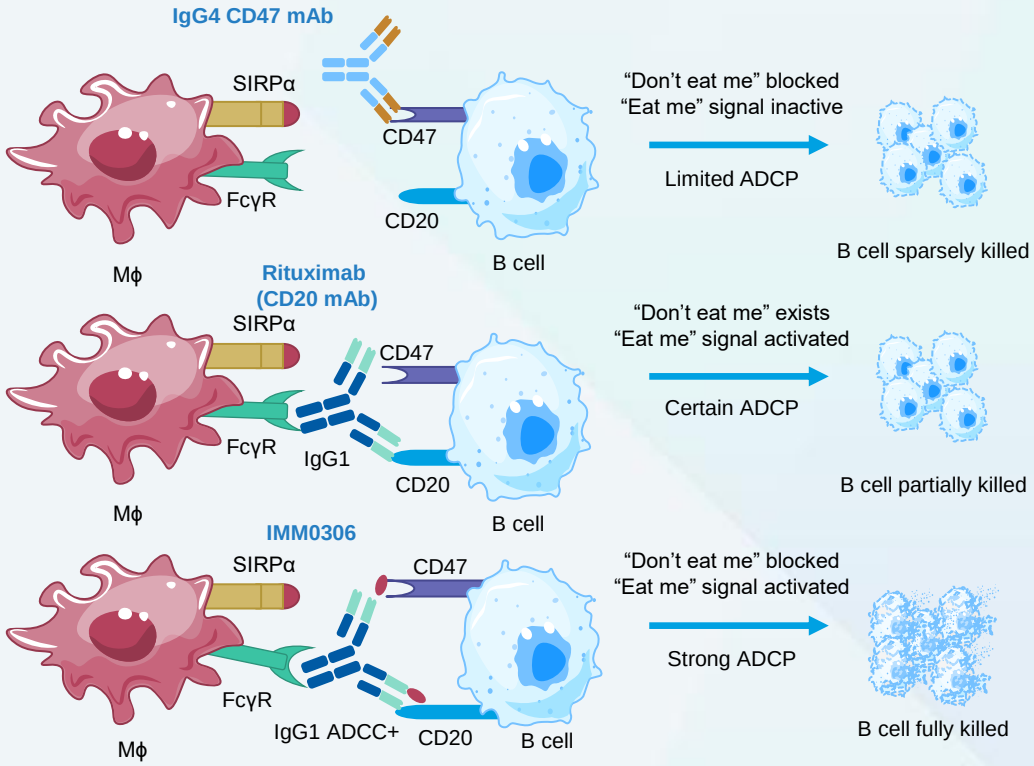
Overview

IMM0306 Molecule Structure



- Full macrophage activation
- Improved ADCP and ADCC activity
- Improved effectiveness for treating patients predominantly expressing FcγRIIIA-158F polymorphism that is less sensitive to CD20 antibody treatment

Mechanism of Action



Market Opportunities and Competition

Unmet needs of R/R B-NHL treatment:

- ✓ CD20 antibody combined with chemotherapy are recommended for 1L & later line treatment
- ✓ However, **approximately 50% of B-NHL patients will eventually relapse**

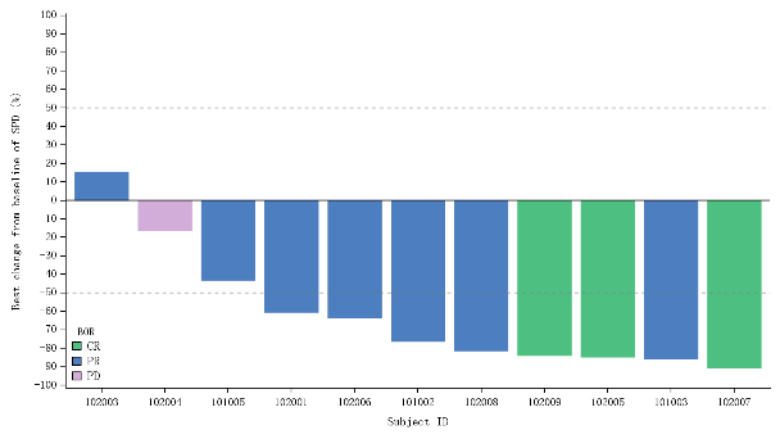
2 CD47×CD20 bispecific antibodies/fusion proteins under development globally
Among them, IMM0306 is the **1st** to enter into a clinical trial

Have great potential in addressing the **unmet needs of R/R B-NHL treatment**

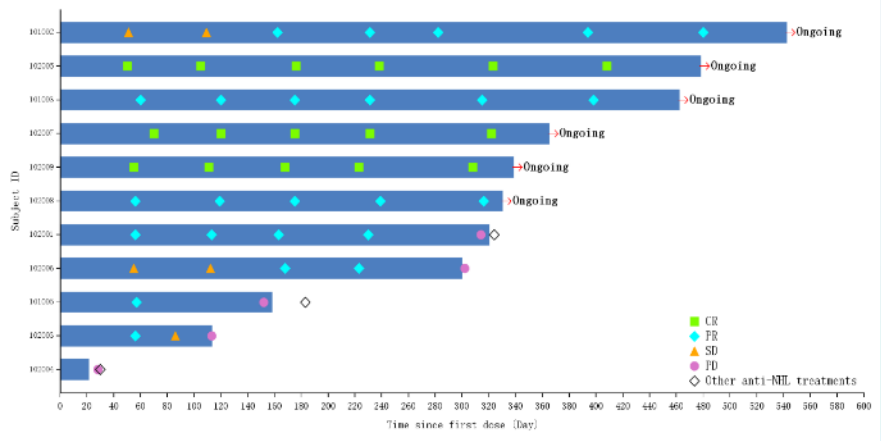
IMM0306 (amulirafusp alfa) (CD47×CD20)

1st CD47 and CD20 Dual-targeting Bispecific to Enter the Clinical Stage Globally

Best Percentage Change from Baseline in Target Lesion in Phase Ib



Duration of Treatment and Response in Phase Ib



Developing In-house and Own its IP and Commercial Rights

5 issued patents in China, Japan, Europe (validated in the ES, CH, DE, FR, GB, IT) and the U.S.

IMM0306 + Lenalidomide Phase Ib

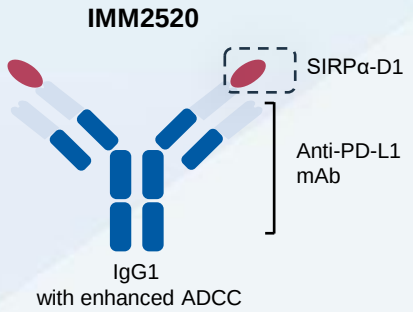
Best Overall Response n (%)	Efficacy Evaluable (N=11)
ORR	10 (90.9)
CR	3 (27.3)
PR	7 (63.6)
PD	1 (9.1)

Source: Company Data; The clinical data is as of Dec 31st, 2024

Note: the data of Phase IIa R/R FL will be presented at ASCO 2025

IMM2520 (CD47×PD-L1)

Overview



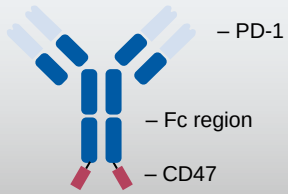
- A CD47 and PD-L1 dual-targeting bispecific molecule for the treatment of solid tumors
- Unique structure to **avoid RBC binding**
- Engineered ADCC-enhanced IgG1 Fc fragment to **fully activate macrophages** and **induce enhanced ADCP and ADCC activity**

Competition Landscape

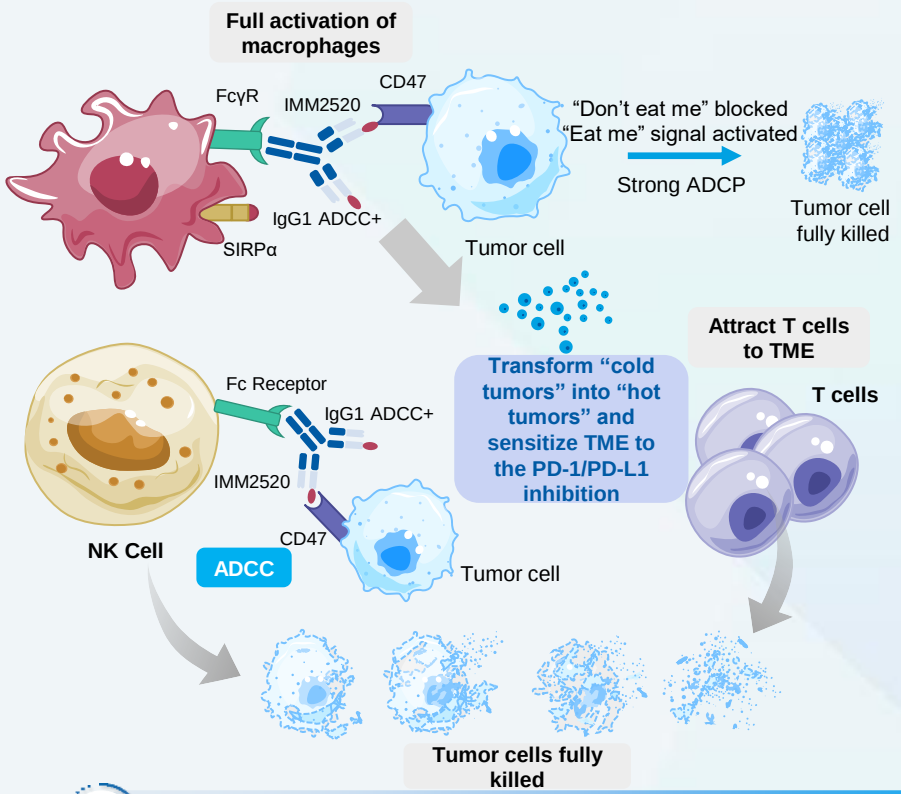
Other 9 CD47 and PD-1/PD-L1 bispecific molecules under clinical development

- ✓ Bispecific molecule formats: certain molecules connect the CD47-binding to the Fc end, which could disrupt immune activation resulted from Fc-FcγR engagement
- ✓ IgG4 Fc: several molecules resort to an IgG4 Fc region with weak FcγR engagement

HX009 (Hans Bio)



Mechanism of Action

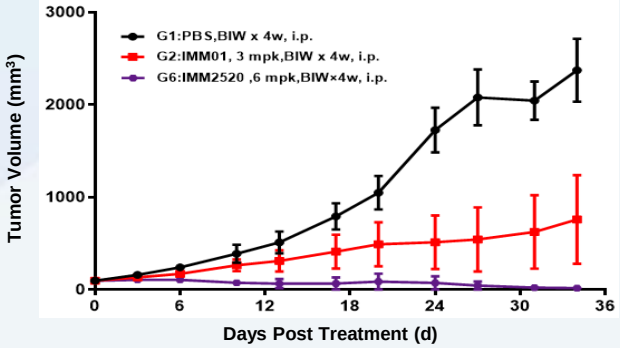


Due to the crosstalk among macrophages, NK cells and T cells, IMM2520 is able to unleash significant synergistic effects

IMM2520 (CD47×PD-L1)

Preclinical Results

Efficacy Study in Colon Cancer (CT26) Mouse Model [1]



Note:
1. IMM2505 is a first-generation CD47 and PD-L1 bispecific molecule internally developed by us; (2) Six mice per group were used in this study
Source: Company data

IMM2520 has also demonstrated **a favorable safety profile**. Its engineered CD47-binding domain shows no binding activity with human RBCs *in vitro*.

Developing In-house and Own its IP and Commercial Rights

- 1 issued patent in Japan
- 1 issued patent in PRC
- 1 issued patent in the U.S.
- Several pending patent applications in Europe, the U.S. Korea and Brazil

Market Opportunities and Clinical Development Plan

Opportunities

A huge market potential for IMM2520

- ✓ **A wide range of cancer indications with high macrophage infiltration**
- ✓ Only about 10% to 25% of patients across almost all major cancer types respond to PD-1/PD-L1 inhibitor monotherapy, including but not limited to **NSCLC, SCLC, CRC, GC, HNSCC, HCC, ESCC, OC, prostate cancer, and pancreatic cancer**

Clinical Development Plan

Have obtained IND approvals from the NMPA in November 2022 and from the FDA in December 2022; Phase I commenced in China in March 2023. Expect to complete this trial in 2024.

Phase I Preliminary Efficacy

As of December 31, 2024, 26 patients have been enrolled and dosed. The preliminary data has demonstrated that IMM2520 is safe and well tolerated. One PR and two SDs with tumor shrinkage over 10% were achieved. The patient had PR was diagnosed as small cell lung cancer who failed for immunotherapy.

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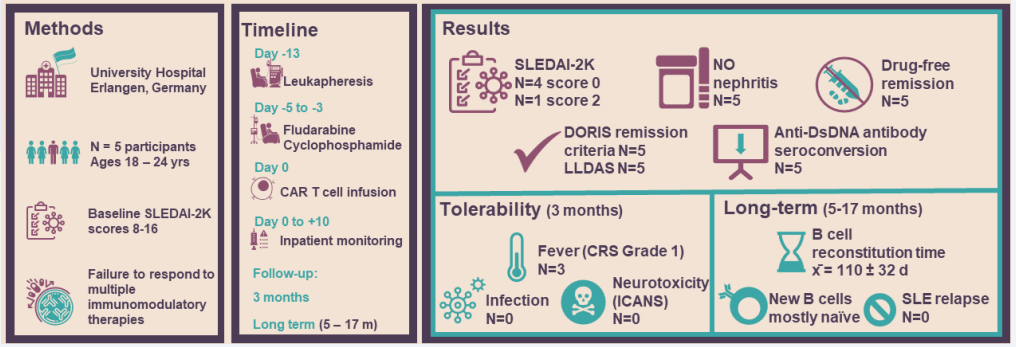
SECTION 3

Non-Oncology Programs

IMM0306 (amulirafusp alfa) (CD47xCD20/mAb-Trap)

B-cell depletion was observed in IMM0306 clinical studies, presents a strong potential in the treatments of autoimmune diseases

A study conducted by Dr. Georg Schett at the University of Erlangen-Nuremberg showed that **deep depletion of B cells** was observed following CD19+ CAR-T treatment in 15 patients, including 8 with systemic lupus erythematosus (SLE), 3 with idiopathic inflammatory myopathies (IIM), and 4 with multiple sclerosis (MS). All patients achieved drug-free remission after the reappearance of B cells, and there were no relapses reported during the 2-year follow-up period.

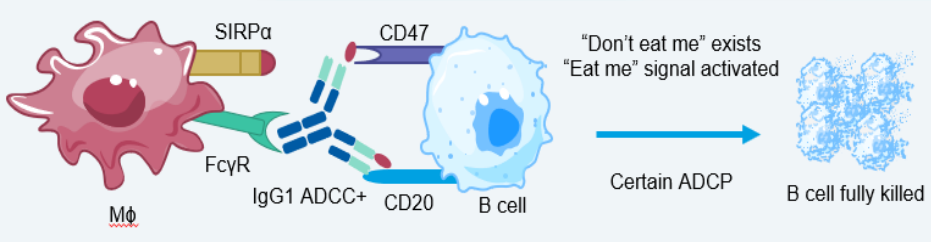


RITUXAN® (rituximab, CD20) was approved by FDA in 2006 for the treatment of **rheumatoid arthritis (RA)**;

BRIUMVI™(Ublituximab, CD20) was approved by FDA in 2022 for the treatment of **multiple sclerosis (MS)**;

B-cell depletion therapies (BCDTs) are widely used in the treatments of autoimmune diseases.

Mechanism of Action

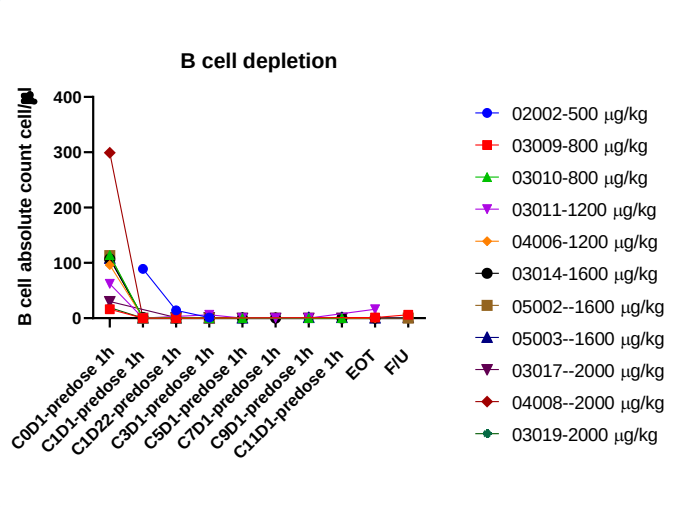


	IMM0306	SIRPα-Fc	CD47 mAb IgG4	Rituximab
ADCP	+++	+++	+	++
ADCC	+++	+	+	++
CDC	++	No	N/A	+++
Induction of hemagglutination	No	No	Yes	Not relevant

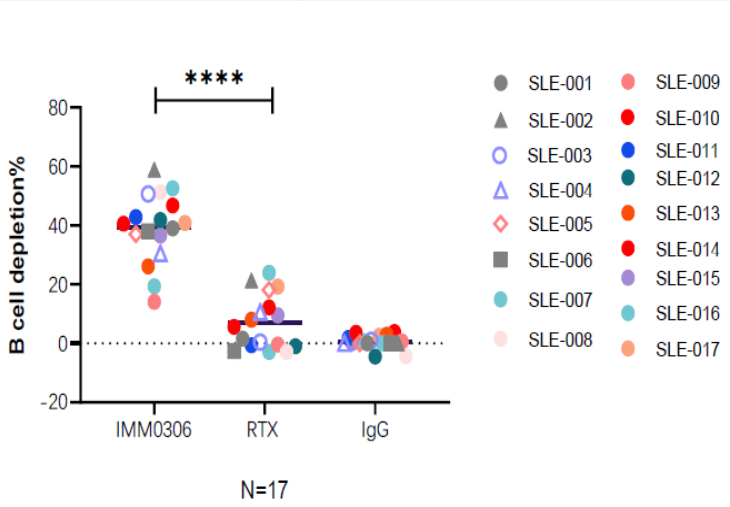
Reference: Dimitrios Mougiakakos, et al., August 5, 2021, N Engl J Med 2021; 385:567-569; Andreas Mackensen, et al. NATURE MEDICINE, VOL 28, Oct. 2022, 2124–2132

IMM0306 (amulirafusp alfa) (CD47xCD20/mAb-Trap)

Peripheral B cell depletion by IMM0306 was observed in a wide range of clinical dose



Stronger B cell depletion capacity than rituximab

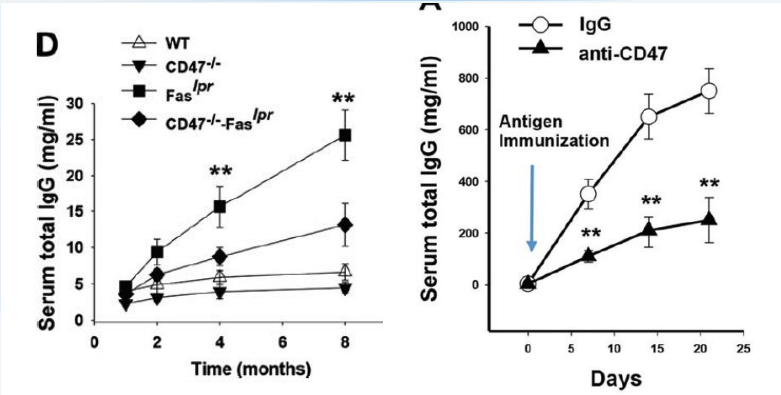


Blood samples from 17 patients with SLE were respectively incubated for 72 hrs with IMM0306 (1μg/ml), Rituximab (RTX) (1μg/ml), or IgG control (1 μg/ml). B cell depletion was analyzed by staining for CD19 and monitored by FACS analysis.

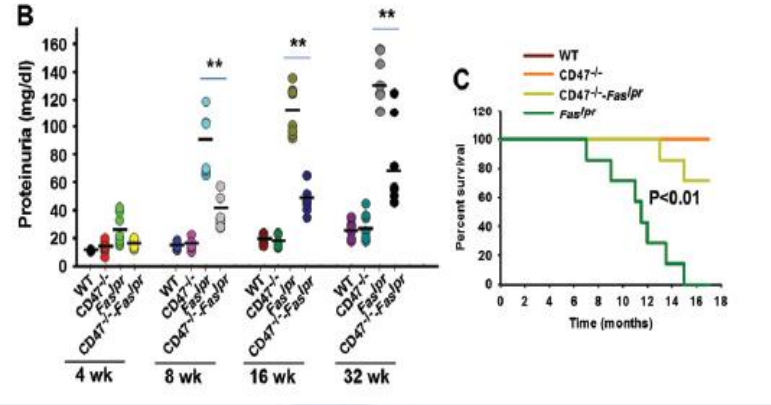
IMM0306 (amulirafusp alfa) (CD47xCD20/mAb-Trap)

CD47 contributes to pathogenesis of lupus nephritis

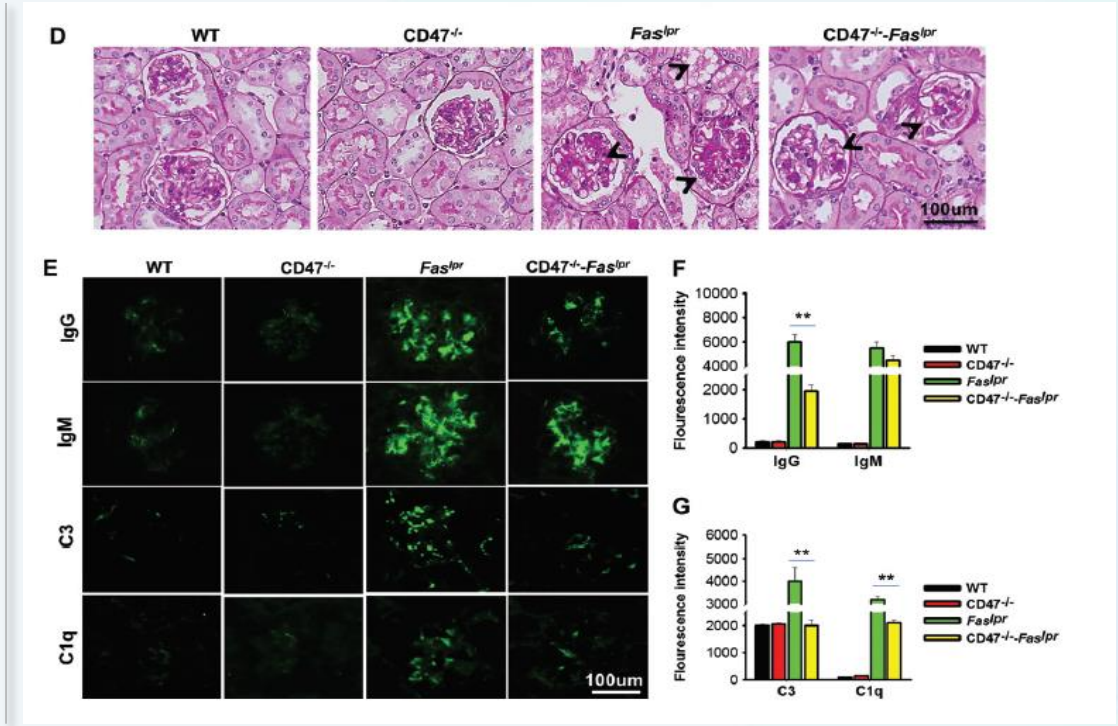
Knockout of CD47 reduces IgG levels and improves lupus nephritis



CD47 knockout in Faslpr LN disease model resulted in decreased proteinuria levels and prolonged survival

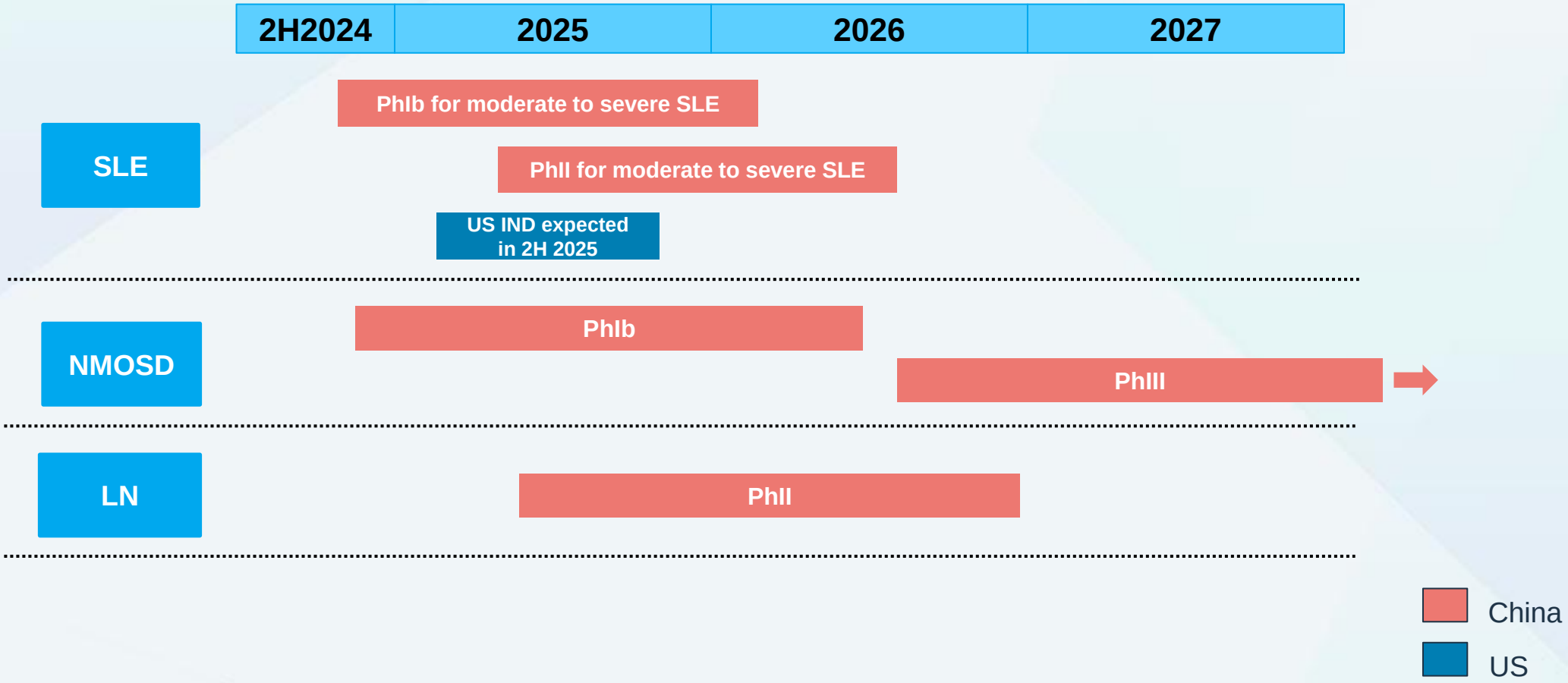


CD47 knockout in Faslpr LN disease model resulted in remission of glomerular base membrane thickening and significantly reduced autoantibodies and complement deposition



IMM0306 (amulirafusp alfa) (CD47xCD20/mAb-Trap)

Potential Global Development Plan



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IMM0306 (amulirafusp alfa) (CD47xCD20/mAb-Trap)

Since 2024, the global business development of innovative BsAb and TsAb in the autoimmune field has been booming

Product	Licenser	Licensee	Upfront and milestone payment	Time	Clinical trial progress
DR-0201 （CD20-directed BsAb MCE [1]）	Dren Bio	Sanofi	Upfront payment of $600 million+ milestone payment of $1.3 billion	2025.3	PhI study in B-NHL patients and is expanding into various autoimmune indications
CN201 (CD3×CD19 BsAb)	Curon Biopharma	MSD	Upfront payment of $700 million+ milestone payment of $600 million	Aug 2024	R/R NHL: PhI; R/R ALL：PhIb/II Autoimmune indications have not yet entered the clinical stage
CMG1A46 (CD3×CD19×CD20 TsAb)	Chimagen Biosciences	GSK	Upfront payment of $300 million+ milestone payment of $550 million	Oct 2024	Hematologic malignancies: PhI/II GSK plans to initiate a PhI trial for lupus in 1H 2025
GB261 (CD20×CD3 BsAb）	Genor Bio	TRC 2004	A double digit million US dollars upfront payment+ up to $443 million in milestone payments	Aug 2024	Completed PhI/II B-NHL（DLBCL&FL） Autoimmune indications have not yet entered the clinical stage
CM336 （BCMA×CD3 BsAb）	Keymed Biosciences	Platina	Upfront and near-term payment of $16 million+ up to $610 million in milestone payments	Nov 2024	R/R MM:PhI/II Platina plans to initiate a PhI trial for the first autoimmune indication in 1H 2025
EMB-06 (BCMA×CD3 BsAb)	EpimAb Biotherapeutics	Vignette Bio	Upfront payment of $60 million in cash and equity +up to $575 million in milestone payments	Sep 2024	R/R MM：PhI/II Autoimmune indications have not yet entered the clinical stage
LBL-051 (CD3 × BCMA ×CD19 TsAb）	Leads Biolabs	Oblenio	Upfront and near-term payment of $35 million +up to $579 million in milestone payments	Nov 2024	IND enabling

Note：PhIb enrollment for IMM0306 in SLE was initiated in Oct 2024 and preliminary data will be disclosed by mid-this year. PhIb enrollment for NMOSD began in Dec 2024. PhIIa enrollment for R/R FL has been completed, and the data will be presented at ASCO 2025

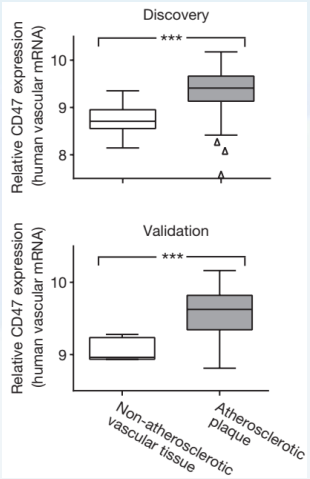
1 MCE-myeloid cell engager

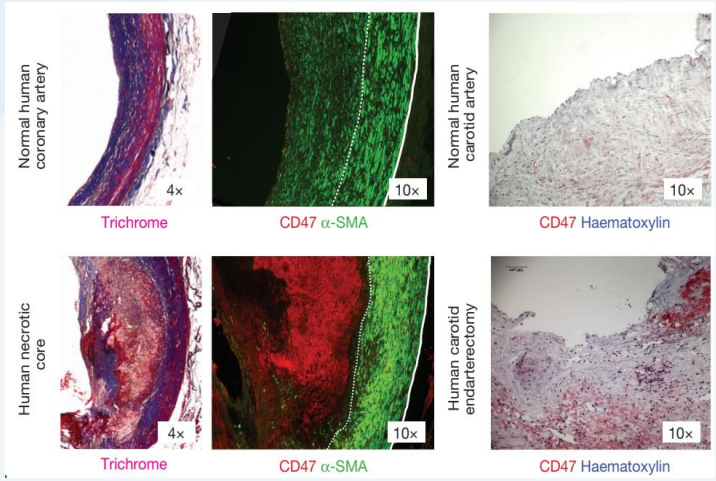
Source: announcements and news of the above companies

IMM01(timdarpacept)

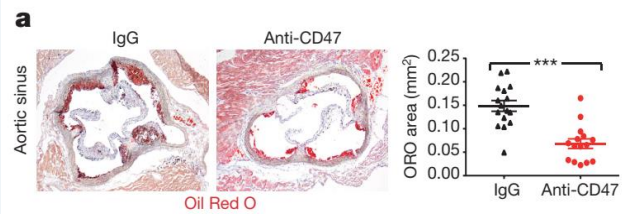
Our CD47-targeted IMM01 presents a strong potential in treating atherosclerosis

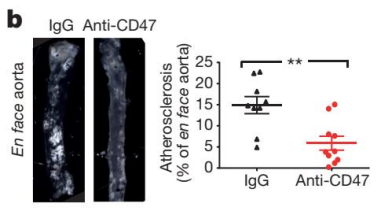
CD47 is highly expressed in human atherosclerotic plaque



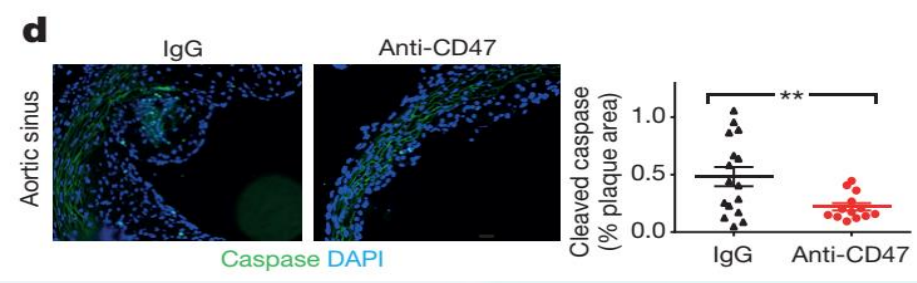


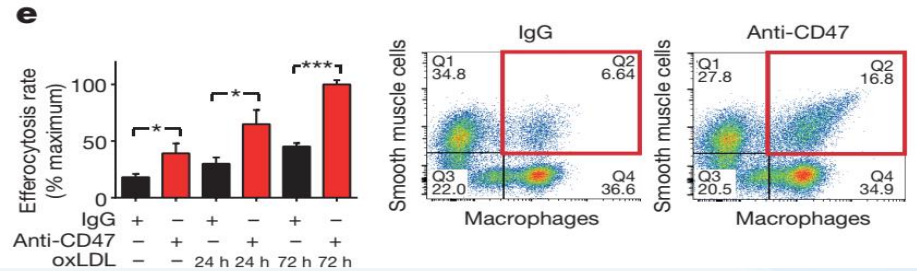
Shrinkage of atherosclerotic plaque was observed in rat model by blocking the CD47/SIRPα signaling pathway

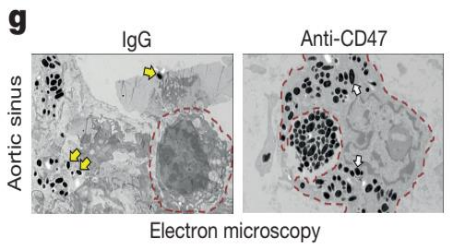




By blocking the CD47 signal, macrophages can phagocytose the atherosclerotic plaque in rat vessel







BITTERROOTBIO

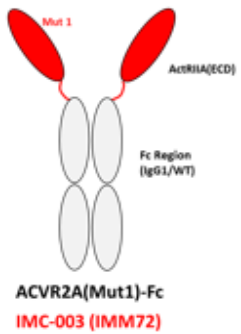
- Bitterroot Bio has one CD47/ SIRRPα that was developed for atherosclerosis
- Bitterroot Bio announced the completion of $145 million round A funding in June 2023
- It was co-founded by Irv Weissmanv, Nick Leeper, John C. Martin and Lou Lange

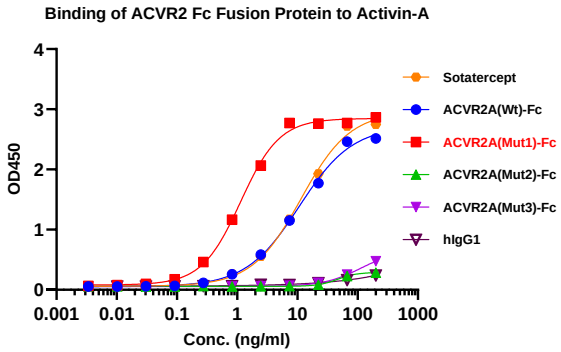
Reference: Yoko Kojima, et al., 86 , Nature, Vol 536, Augest 2016;

IMC-003 (IMM72, ActRIIA/Fc-fusion)

Preclinical Results

Compared to Sotatercept, IMC-003 has stronger binding and blocking capacity

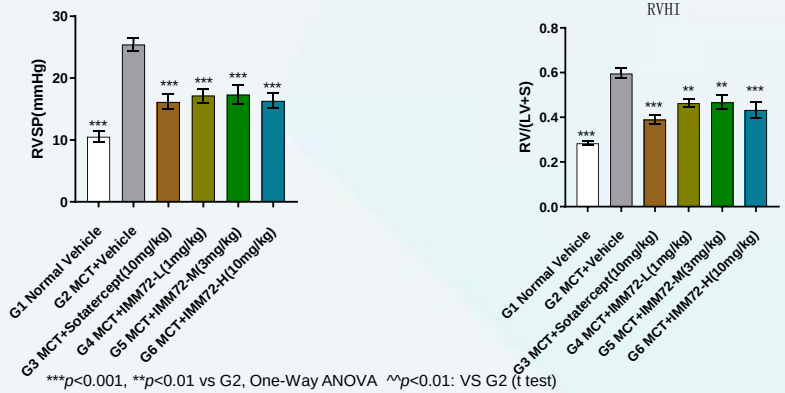




	Sotatercept	ACVR2(WT)-Fc	ACVR2(Mut1)-Fc
EC50	11.43	10.70	1.140

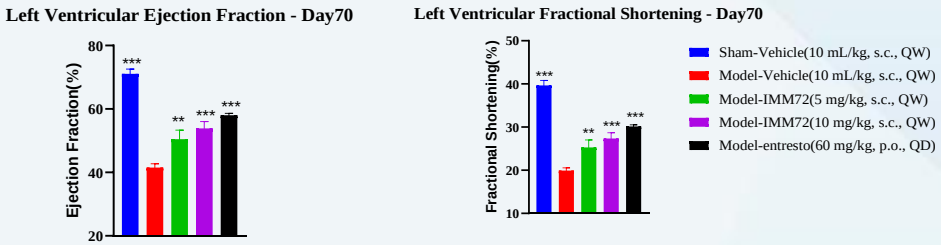
	IMC-003 (IMM72)	Sotatercept
Company	ImmuneOnco	MSD
Structure	ACVR2A-Fc (point mutation)	ACVR2A-Fc
Affinity	Comparable	Comparable
Binding (ELISA)	Stronger (≥7 times)	Medium
Blocking	Stronger	Medium
In vivo efficacy	Stronger	Medium

IMC-003 exhibits good efficacy in MCT induced PAH model



***p<0.001, **p<0.01 vs G2, One-Way ANOVA ^^p<0.01: VS G2 (t test)

IMC-003 exhibits good efficacy in a TAC model of heart failure



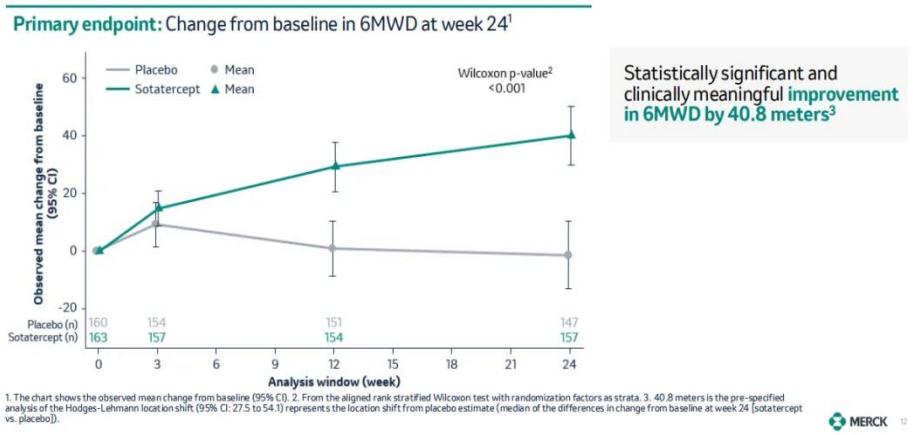
**p<0.01, ***p<0.001: VS G2(One-way ANOVA/Dunnett's)

IMC-003 (IMM72, ActRIIA/Fc-fusion)

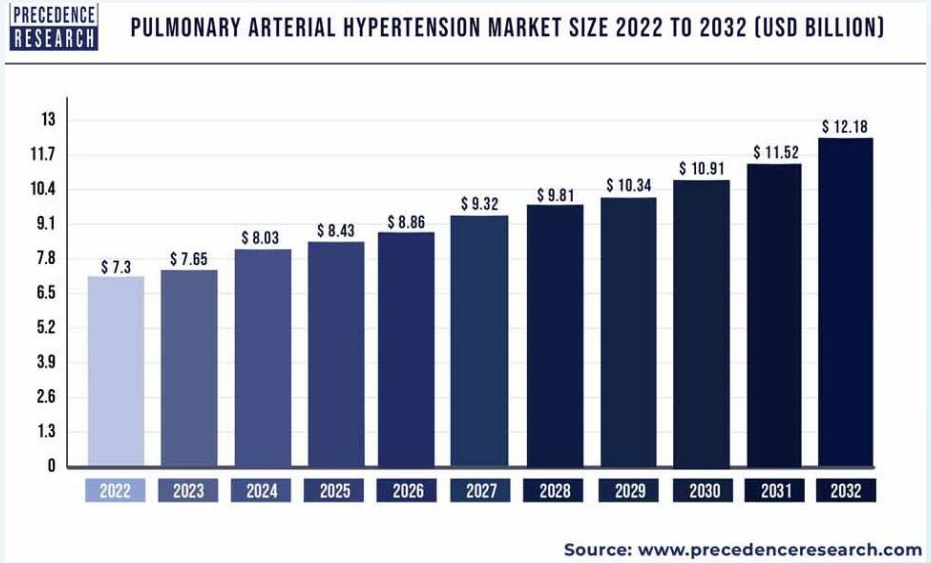
Pulmonary Arterial Hypertension (PAH) Market Potential

Sotatercept is the only approved drug that can reverse disease progression

STELLAR: sotatercept significantly improve 6-minute walk distance at week 24



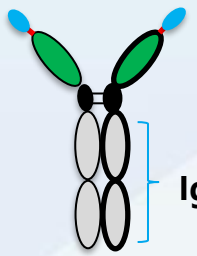
The global PAH market size reached USD 7.3 billion in 2022 and is expected to hit around USD 12.18 billion by 2032



- Sotatercept (brand name: WINREVAIR ）was approved for marketing by the FDA on March 26, 2024, and achieved strong sales of **$419 million** in 2024
- IMC-003 has completed pre-IND communication and is expected to receive IND approval in June 2025 from the CDE, making it the fastest progressing innovative molecule with the same target for the treatment of PAH in China, aside from sotatercept (currently in BLA stage)

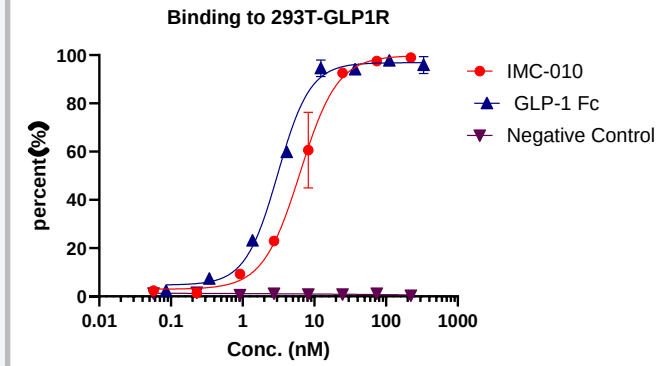
IMC-010 (IMM7220, GLP-1x ActRIIA Fc-fusion protein)

A Bispecific molecule Targeting GLP-1 and ActRIIA with Global First-in-Class Potential

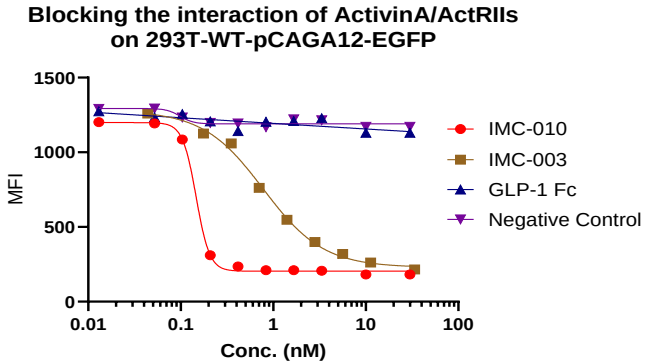


- **IMC-010 (IMM7220)** is expected for the better treatments of Metabolic decrease, by targeting both **GLP-1** and **ActivinA/ActRIIs signaling pathway**. We are proceeding with in vivo efficacy study.
- **IMM7220's** blocking activity for Activin A/ActRIIs pathways is enhanced to around 5 folds over that of **IMM72.**

Activity



	IMC-010	GLP-Fc
EC50	6.344	3.089

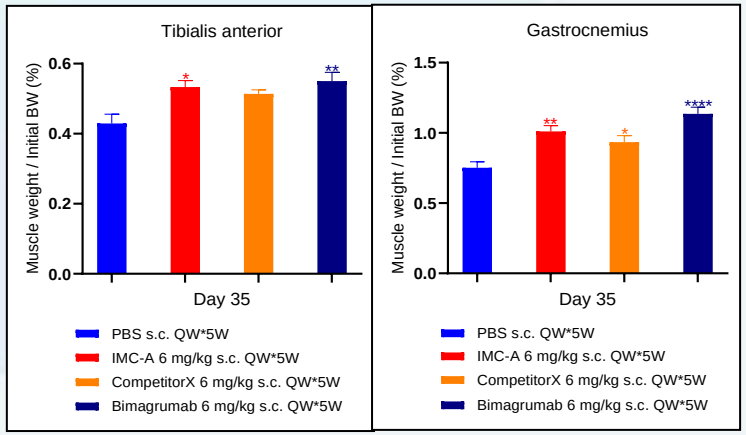


	IMC-010	IMC-003
IC50	0.1466	0.7803

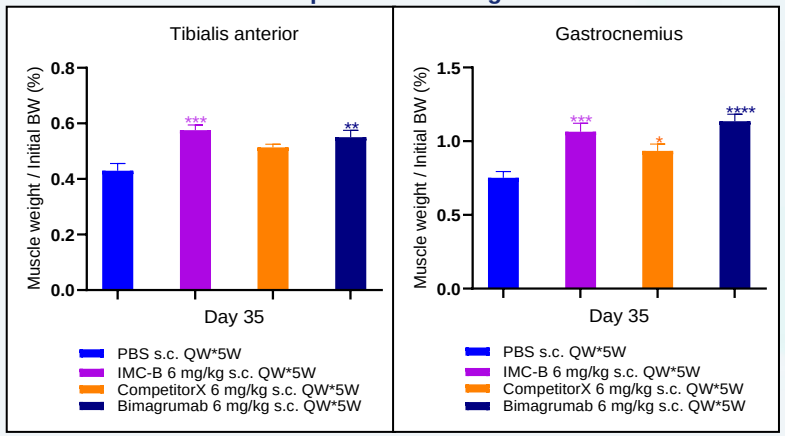
Innovative Molecule Matrix Targeting ActRIIA/B

In CB17-SCID mouse model, our candidates showed significant increase in muscle mass after once-weekly administration for 5 weeks

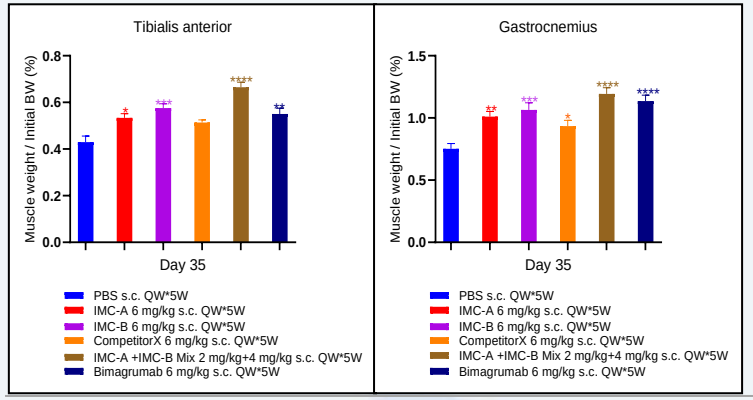
Candidate A's efficacy was better than competitorX



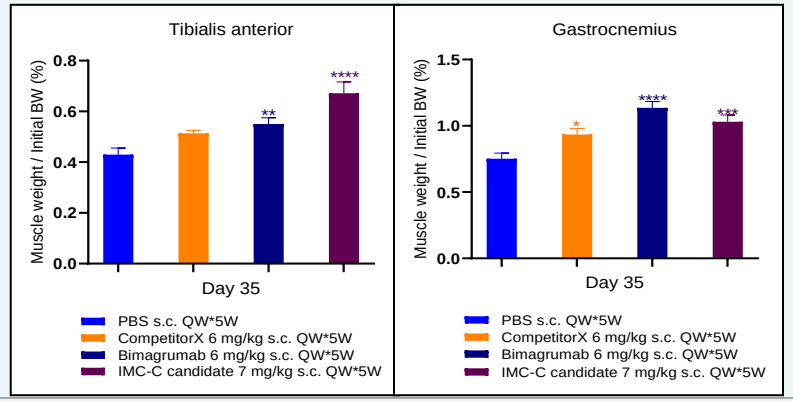
Candidate B's efficacy was superior to competitorX and comparable to bimagrumab



Combo of candidate A and B exhibits the optimal efficacy



Candidate C can significantly increase muscle weight



a, Mean ± SEM; N=6.
b, p value was calculated based on different groups of muscle mass using vehicle group as the control by T-Test. *p<0.05; **p<0.01; ***p<0.001; ****p<0.0001.

IMC-A, IMC-B, IMC-C represents our candidate A(mAb), candidate B(mAb) and candidate C (BsAb) respectively.

IMC-010 (IMM7220, GLP-1x ActRIIA Fc-fusion protein)

ActRII biology in reducing fat mass while preserving muscle mass

ActRII biology in adipose tissue

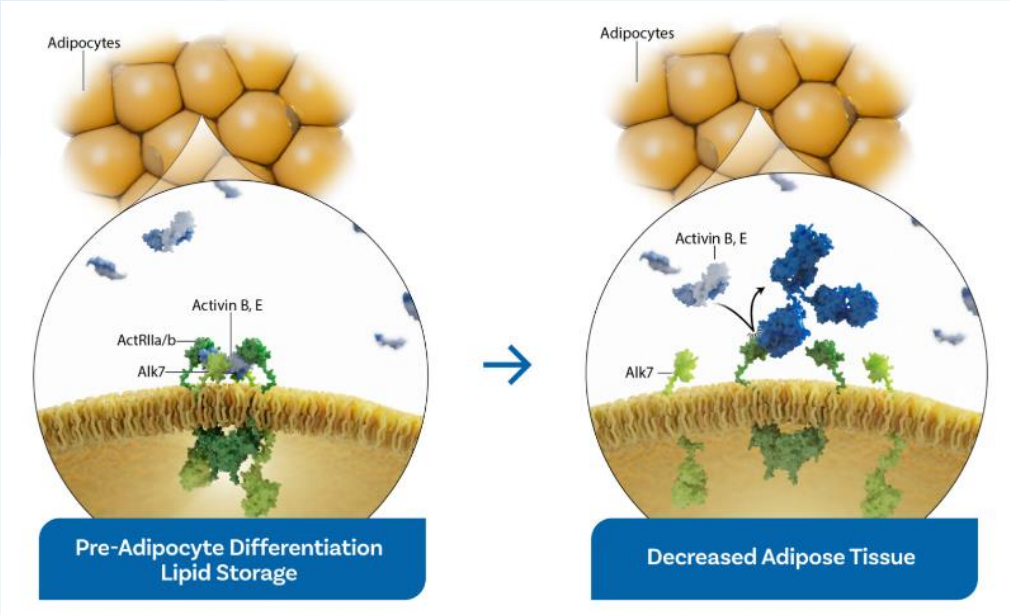
Activin signaling via ActRII receptors directly promotes lipid storage, acting as a key driver of visceral fat accumulation and obesity

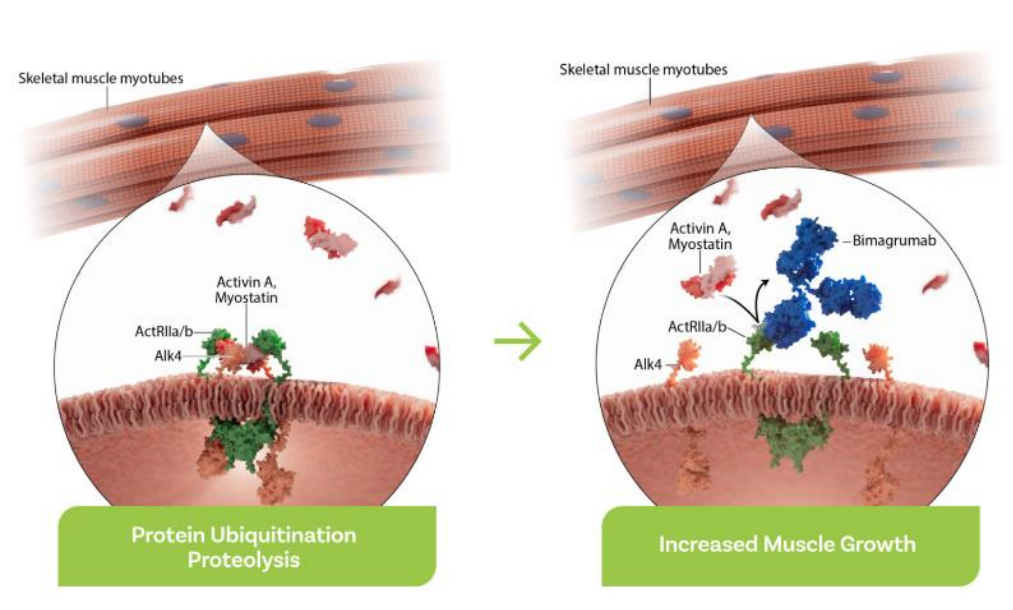
By blocking ActRII signaling in adipose cells, can mobilize and metabolize fat.

ActRII biology in muscle tissue

Signaling via ActRII receptors inhibits muscle growth and promotes atrophy.

Blocking activin signaling in skeletal muscles inhibits this atrophy and can promote increases in muscle mass, helping patients with obesity improve body composition and metabolism while losing fat.



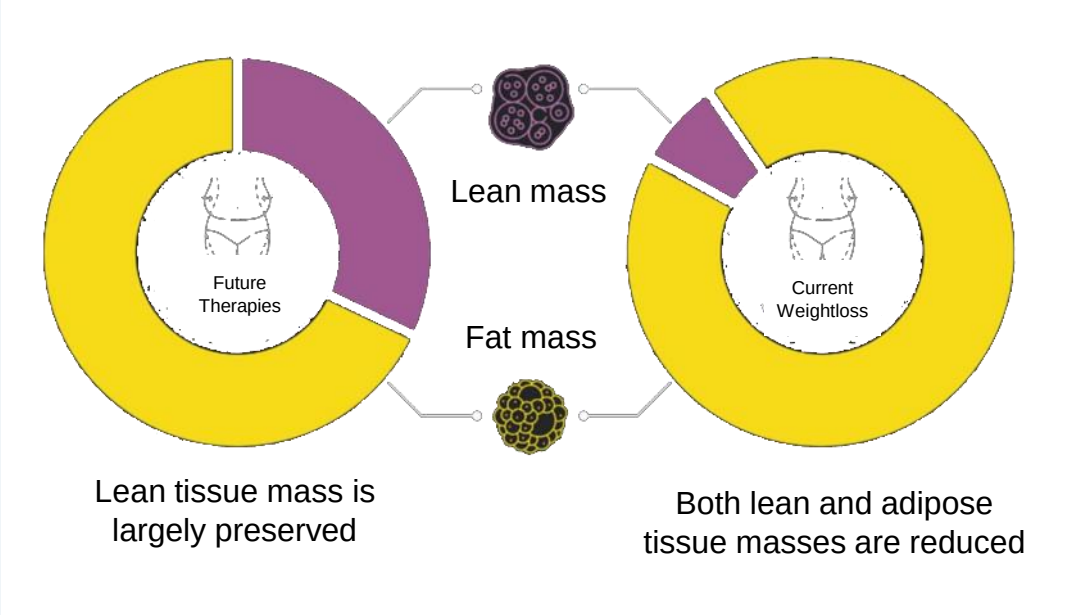


Reference: versanisbio.com

IMC-010 (IMM7220, GLP-1x ActRIIA Fc-fusion protein)

Obesity market and future therapies

- Obesity market was valued at **$140.3 billion** in 2023 and would reach to **$351.8 billion** in 2033.
- Future therapies required adipose mass reducing but lean mass preserving.



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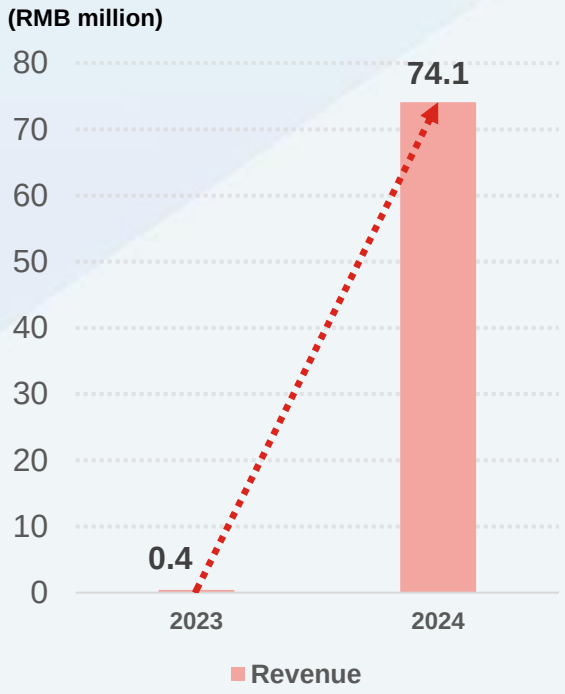
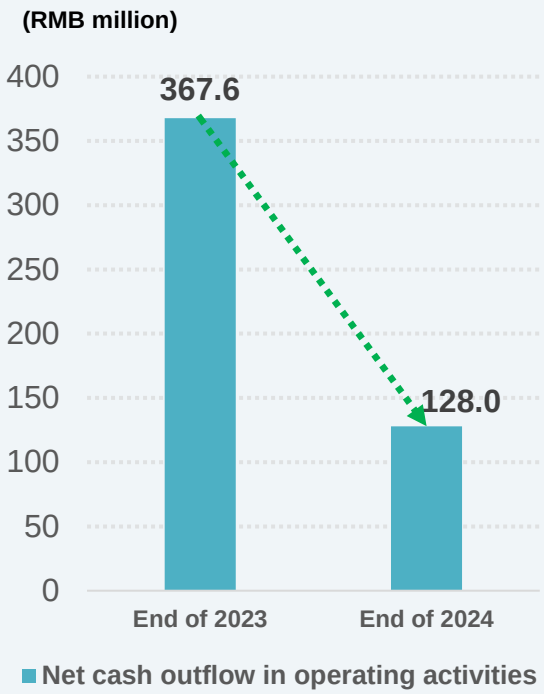
SECTION 4

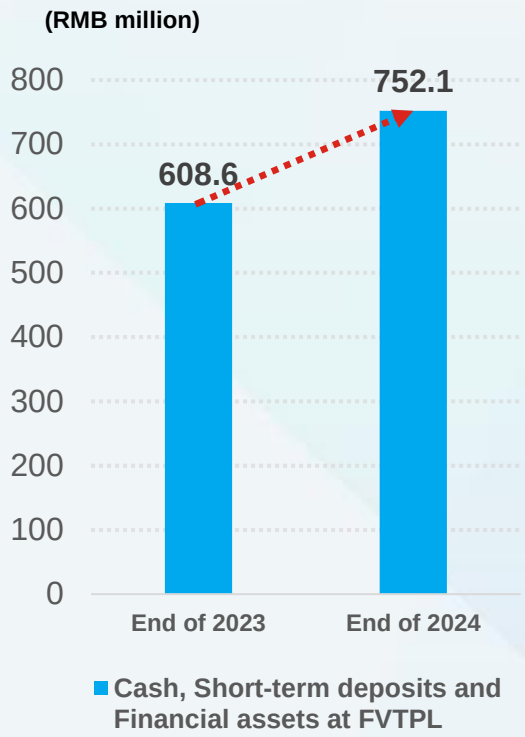
Financial Highlights

Financial Highlights

Our cash position increased to 752.1 million mainly due to the cash inflow of Out-licensing (RMB106.9mm) and the Placing (RMB212.3mm)







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APPENDIX :

Our Approach

Breaking Drug Resistance and Broaden Benefit

Research Has Shown PD-1/PD-L1 Inhibitors Are Only Expected to be Effective in Hot Tumors, Corresponding to its Limited Monotherapy Response Rates, The Activation of Innate Immune Cells is Able to Attract T Cells into Tumor Microenvironment, Turning Cold Tumors to Hot Tumors, Significantly Improve the Response Rates of PD-1/PD-L1 Inhibitors

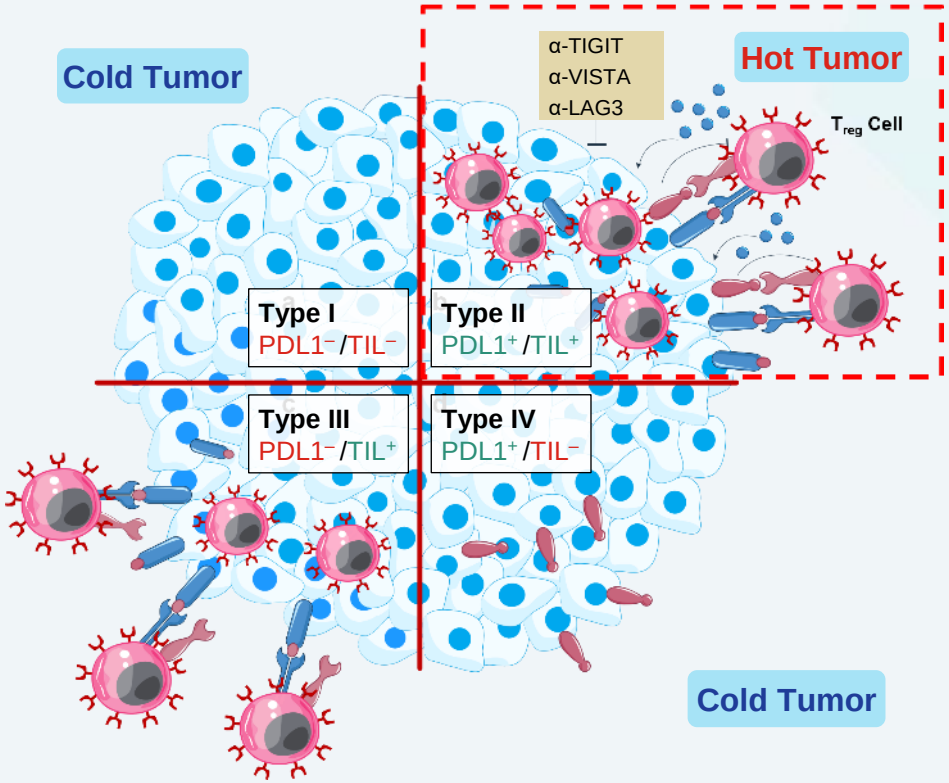
Type I

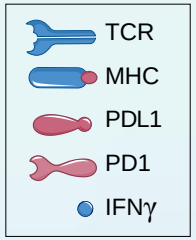
Lack of TILs in TME

Innate immune activation to induce inflammation and attract adaptive immune cells

Type II

Overregulation of activated TILs





Type III

Dysfunctional TILs activation

Activation of antigen specific T cells through antigen presenting cells

Type IV

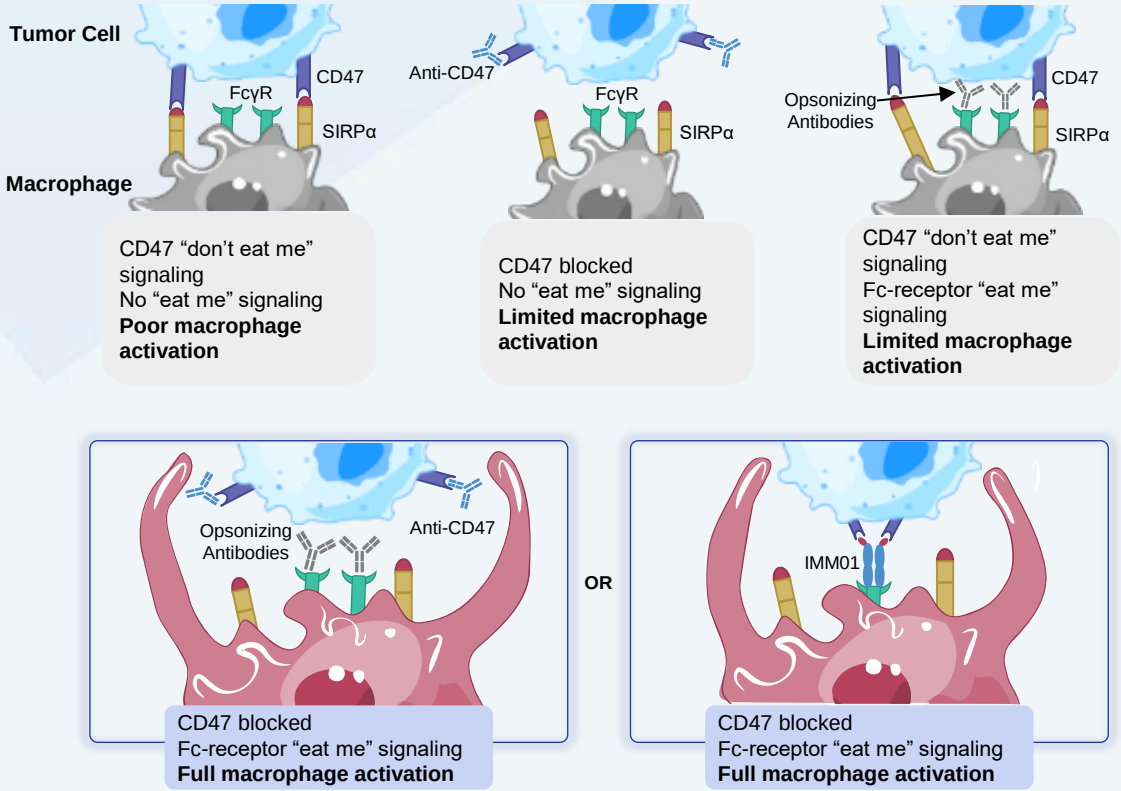
Lack of TILs in TME

Innate immune activation to induce inflammation and attract adaptive immune cells

Source: Frost & Sullivan, literature review

Scientifically and structurally differentiated molecule design based on our “drug-by-design (DbD)” concept to achieve potent efficacy and favorable safety

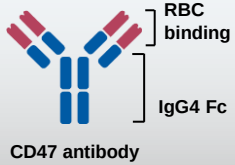
Mechanism of Action in the CD47-SIRPα Signaling Pathway



Guided by the DbD concept, our **differentiated molecule design** tackles scientific barriers presented by the selected immune checkpoints, leading to an **optimized safety and efficacy profile**

How Our Differentiated Design Improves Safety and Efficacy

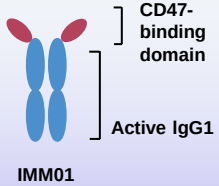
The safety concerns around CD47 pose considerable challenge



CD47 antibodies inevitably bind with RBCs, generating issues including **severe blood toxicity**, **antigenic sink**, and **decreased potency**

Most CD47 antibodies resort to an **IgG4 Fc with weak FcγR engagement**, unable to deliver the “eat me” signal

Our differentiated design allows full macrophage activation

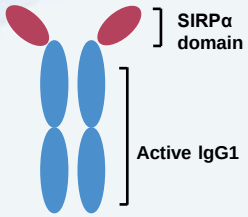


Engineered CD47-binding domain with **no RBC binding** *in vitro;* Modification of deglycosylation of the binding domain **mitigates immunogenicity**

No RBC binding enables usage of **potent IgG1 Fc**

Overview and Competitive Advantage of IMM01 (Timdarpacept)

Overview

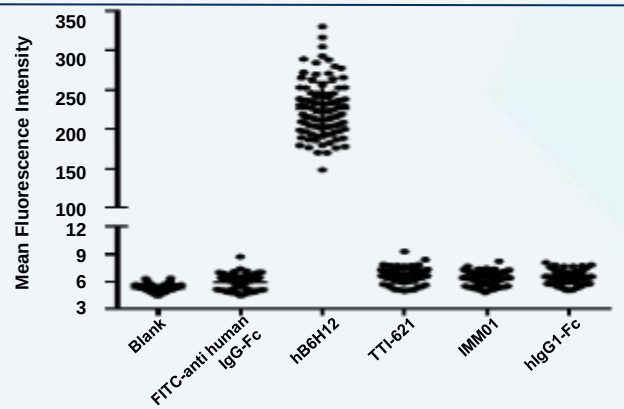


- First SIRPα-Fc fusion protein to enter the clinical stage in China
- Improved safety profile with engineered CD47-binding domain of human SIRPα to avoid human RBC binding
- Designed to fully activate macrophages through a dual mechanism
- Encouraging single-agent efficacy at relatively low dose, with CR observed

Source: Company Data

Competitive Advantage of IMM01 Monotherapy - Safety

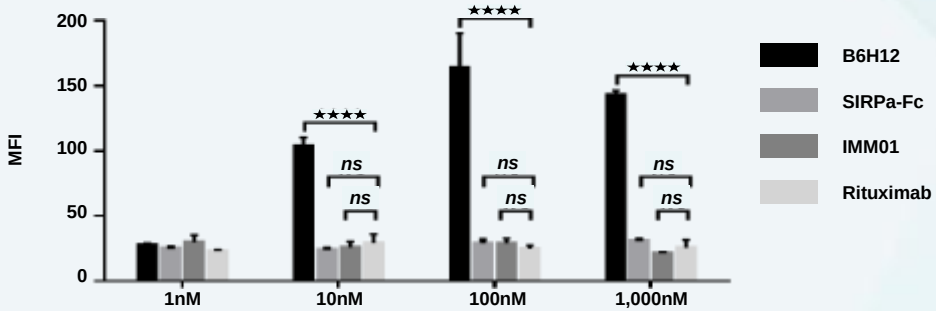
Human RBC Binding Analysis of IMM01



Donor Characteristics (n=100)
Male (n=62)
Female (n=38)
Type A blood group (n=29)
Type B blood group (n=31)
Type AB blood group (n=10)
Type O blood group (n=30)
hB6H12: 500nM
TTI-621: 5000nM
IMM01: 5000nM
hIgG1-Fc: 5000nM

Notes: B6H12 is a CD47-based antibody that serves as the control.

Phagocytosis Against Human RBC

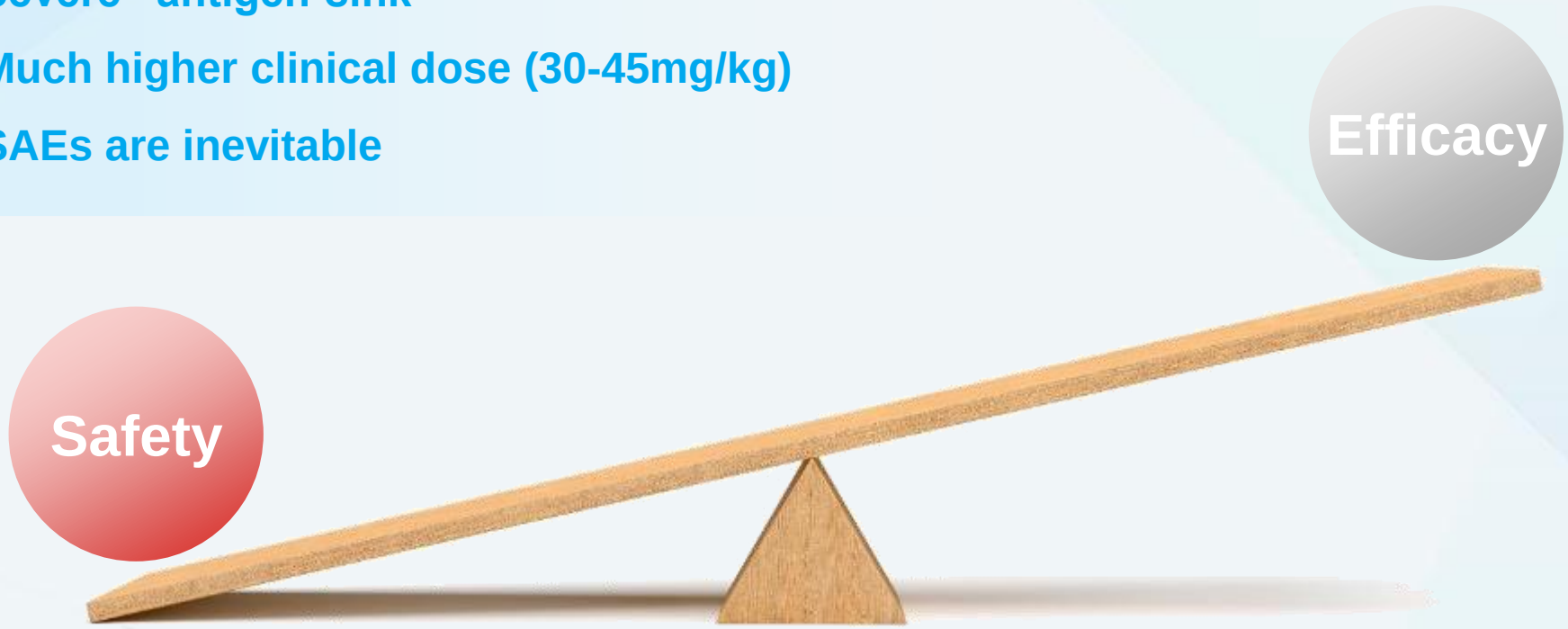


Notes: B6H12 is a CD47-based antibody that serves as the control.

Challenges for CD47-Targeted Drug Development

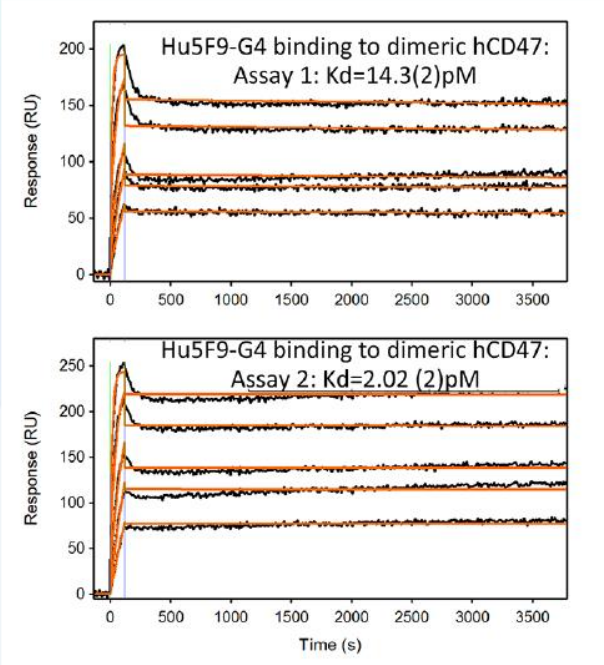
CD47 Antibody

- Target affinity is too high
- Severe “antigen-sink”
- Much higher clinical dose (30-45mg/kg)
- SAEs are inevitable

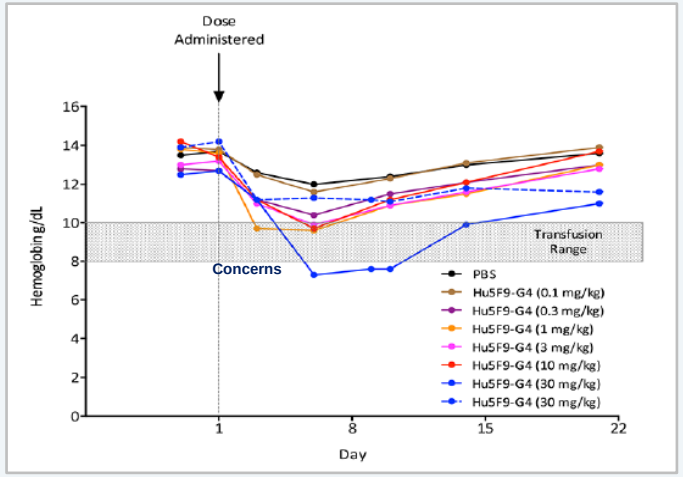


Magrolimab Has Very High Target Affinity and RBC Binding Activity

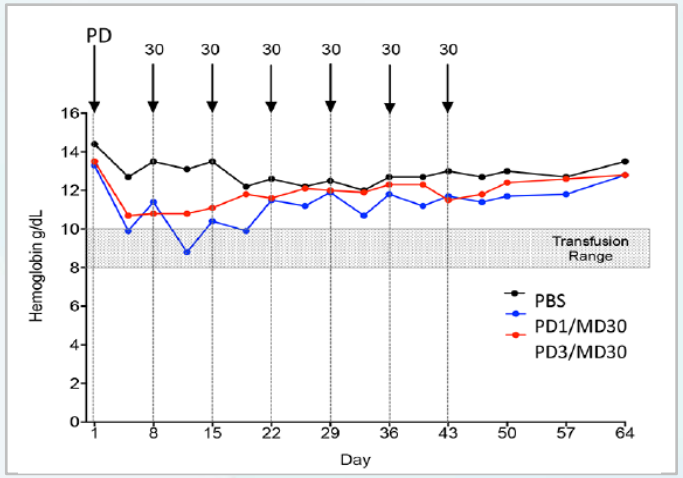
Target affinity assay



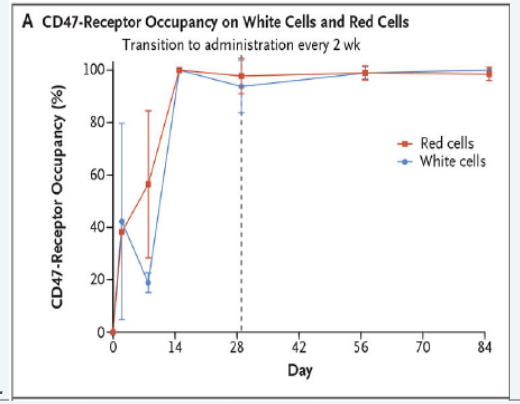
Without priming dose



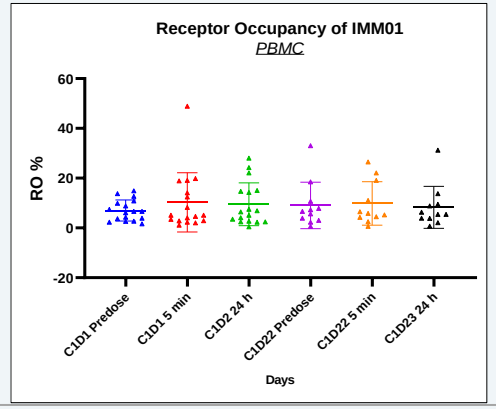
With priming dose (1mpk, 3mpk)



Magrolimab Receptor Occupancy (RO)



IMM01 Receptor Occupancy (RO)



Concerns

- Bind to RBC, leading to hemolysis
- Too high target affinity, causing severe "antigen sink"
- High clinical dose is required due to the "antigen sink"
- High clinical dose will inevitably results in severe adverse event (SAE)

Magrolimab: KD = 2-14.3pM

Timdarpacept (IMM01): KD = ~3nM

Source: Liu et al. PLoS One. 2015 Sep 21;10(9):e0137345.

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Thank you!