宜明昂科
ImmuneOnco

ImmuneOnco
2024 ASCO Data

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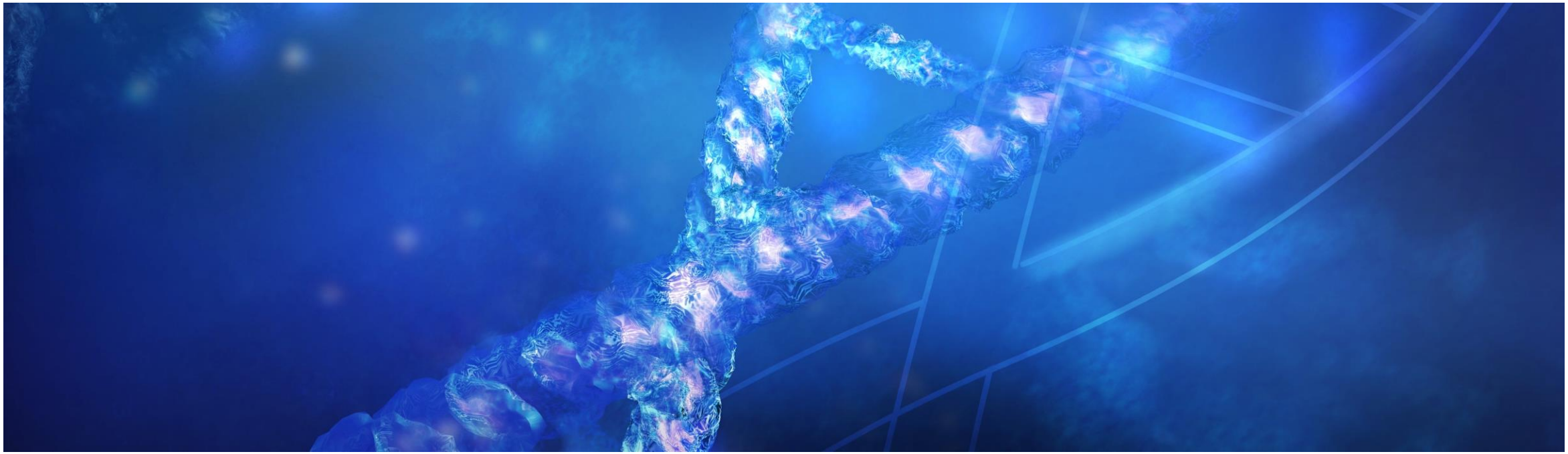
Pipeline

Program [1]	Target (Modality)	Indication(s)	Discovery	Preclinical	IND/IND-Enabling	Phase Ia/I	Phase Ib/II	Phase III/ Pivotal	Current Status / Upcoming Milestone	Commercial Rights
IMM01										
IMM01 + Azacitidine	CD47 (SIRPα-Fc fusion protein)	MDS	China (NMPA)						Received Phase III approval from CDE in May; initiated Phase III trial	Global
IMM01 + Azacitidine	CD47 (SIRPα-Fc fusion protein)	CMML[2]	China (NMPA)						Received Phase III approval from CDE in June; initiated Phase III trial	Global
IMM01 + Tislelizumab	CD47+PD-1	cHL[3], Solid tumor	China (NMPA)						Received Phase III approval from CDE in April; initiated Phase III trial	Global
IMM0306 Monotherapy	CD47xCD20 (Bispecific)	R/R FL&MZL	China (NMPA)						Phase II trial commenced in Q2 2023	Global
IMM0306 + Lenalidomide	CD47xCD20 (Bispecific)	B-NHL	China (NMPA)						Phase Ib/IIa commenced in June 2023 in China	Global
IMM2510 Monotherapy	VEGFxPD-L1 (Bispecific)	STS	China (NMPA)						Phase Ib/II commenced in November 2023 in China	Global
IMM2510 + Chemo	VEGFxPD-L1 (Bispecific)	1L TNBC, 1L NSCLC	China (NMPA)						IND approved in China in November 2023	Global
IMM2510 + IMM27M	VEGFxPD-L1 (Bispecific) + CTLA-4	2L HCC, TNBC	China (NMPA)						IND approved in China in October 2023	Global
IMM27M	CTLA-4 ADCC+ (mAb)	Solid tumors	China (NMPA)						Phase I completed in September 2023 in China and RP2D was identified as 5mg/kg	Global
IMM2902	CD47xHER2 (Bispecific)	HER2-positive and low-expressing solid tumors	China (NMPA), US (FDA)						Phase Ia commenced in February 2022 in China and in June 2022 in the U.S.	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 and 5th cohort ongoing	Global
IMM47	CD24 (mAb)	Solid tumors	China (NMPA), US (FDA)						IND approved in China and the U.S. in October and December in 2023; Phase I commenced in September 2023 in Australia	Global
IMM40H	CD70 (mAb)	Liquid/Solid tumors	China (NMPA), US (FDA)						IND approved in China and the U.S. in August 2022	Global
IMM4701	CD24xCD47 (Bispecific)	Solid tumors	China (NMPA), US (FDA)						IND-enabling	Global
IMC-002 (IMM0306)	CD47xCD20 (Bispecific)	Undisclosed							Filed IND application with the NMPA in March 2024	Global
IMC-001 (IMM01)	CD47 (SIRPα-Fc fusion protein)	Undisclosed							IND-enabling	Global
IMC-003 (IMM72)	ActRIIA (Fc-fusion protein)	PAH, Undisclosed							IND-enabling in one year	Global
IMC-004 (IMM7211)	ActRIIA x Non-disclosed (Bispecific)	Undisclosed							IND-enabling in one and a half year	Global

Innate Immunity Targets | **Innate and Adaptive Immunity Targets** | **Adaptive Immunity Targets** | **Autoimmune and 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 cohort-expansion trials of this combination are 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), unfit AML (individuals of older age with AML who are considered not eligible for intensive treatment approaches), and CMML. On November 8, 2023, the combination therapy of IMM01 and Azacitidine was granted the orphan-drug designation by the FDA for the treatment of CMML
(3) This combination of IMM01 and tislelizumab targets all subtypes of cHL

1 Latest Results of a Phase 2 Study of IMM01 Combined with Azacitidine (AZA) As the First-Line Treatment in Adults with Higher Risk Myelodysplastic Syndromes (MDS)



Introduction

- CD47 is an innate immune checkpoint that binds signal regulatory protein alpha (SIRPα) , and serves as a mechanism of immune surveillance evasion and suppress macrophage phagocytosis[1,2].
- IMM01 (Timdarpacept) is a SIRPα IgG1 fusion protein that exerts anti-tumor activity via blocking “Don't eat me” signal and activating the "Eat me" signal to induce strong antibody-dependent cellular phagocytosis (ADCP)[3]. (Fig.2)

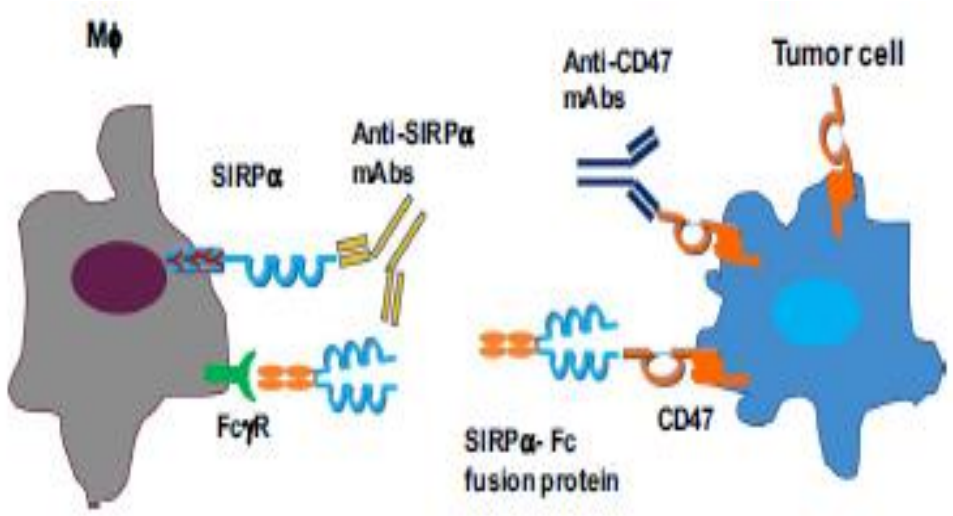


Fig.1 The mechanism of CD47-SIRP α

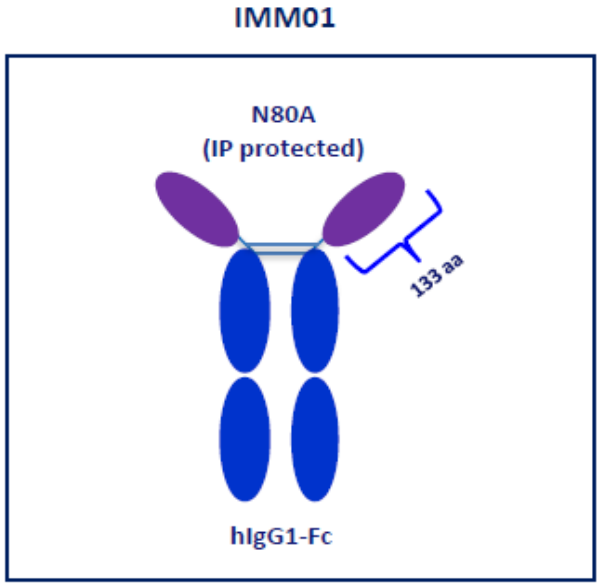
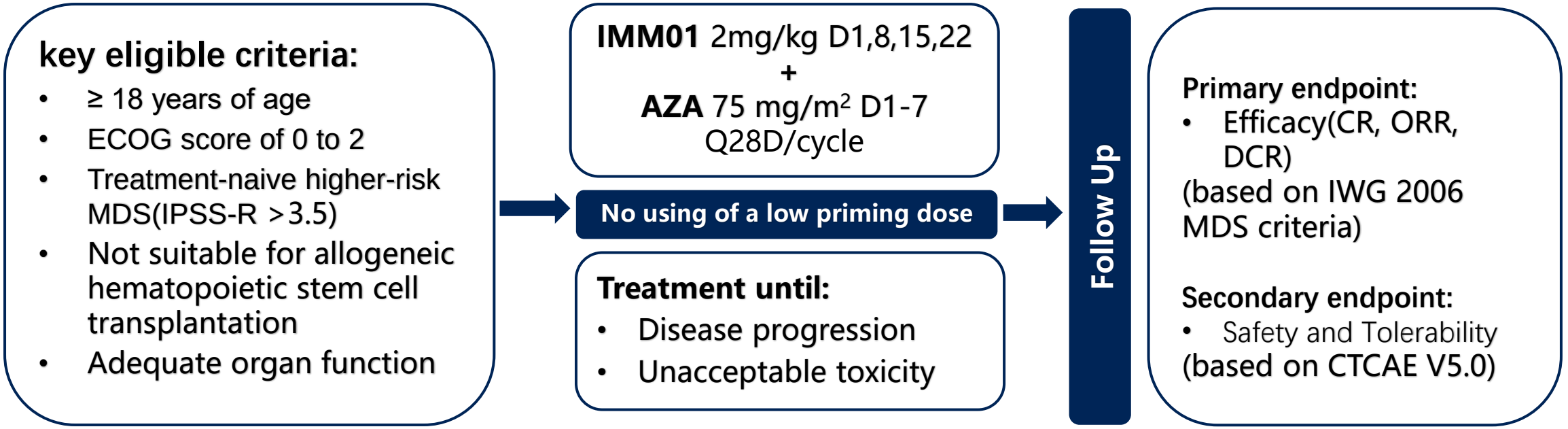


Fig.2 The Structure of IMM01（Timdarpacept）

1. Jaiswal S, et al. Cell 2009;138:271–85.
2. Majeti R, et al. Cell 2009;138:286–99.
3. Jifeng Yu, et al. J Hematol Oncol . 2022;15:167.

Study Design

This is an open-label, multi-center, phase 2 study (NCT05140811) that evaluated safety and efficacy of IMM01 (Timdarpacept) in combination with AZA as the first-line treatment for patients with higher-risk MDS.



Baseline Characteristics of Patients

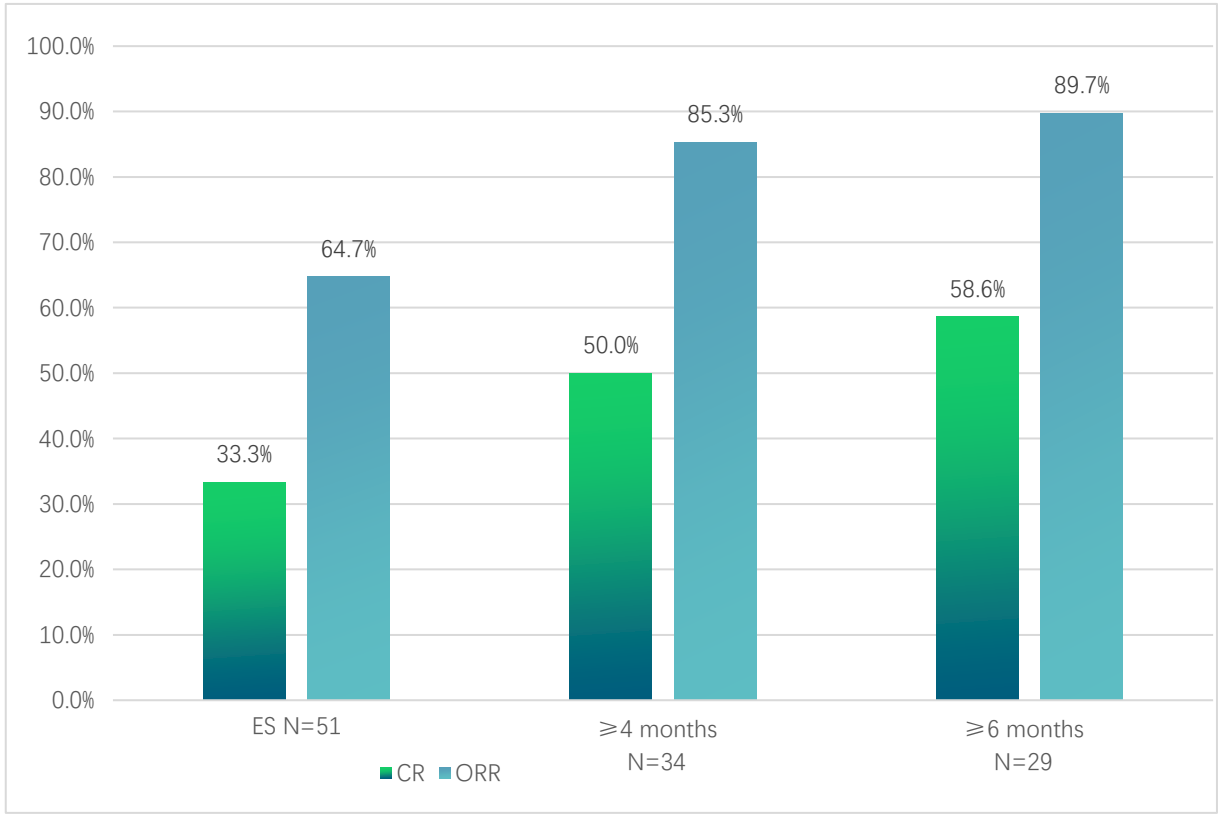
Characteristics	1L MDS (N =57)
Median age, yrs (range)	64 (30-83)
Gender	
Male	41 (71.9%)
Female	16 (28.1%)
ECOG Performance Status, n (%)	
0	2 (3.5%)
1	47 (82.5%)
2	8 (14.0%)
IPSS-R classification	
Intermediate risk (>3.0 - ≤4.5)	14 (24.6%)
High risk (>4.5 - ≤6.0)	25 (43.9%)
Very High risk (>6.0)	18 (31.6%)
2016 WHO of MDS (Subtype)	
MDS with single lineage dysplasia (MDS-SLD)	0
MDS with multilineage dysplasia (MDS-MLD)	6 (10.5%)

Characteristics	1L MDS (N =57)
2016 WHO of MDS (Subtype)	
MDS with ring sideroblasts (MDS-RS)	1 (1.8%)
MDS with excess blasts-1 (MDS-EB-1)	20 (35.1%)
MDS with excess blasts-2 (MDS-EB-2)	22 (38.6%)
MDS, unclassifiable (MDS-U)	2 (3.5%)
Unknown	6 (10.5%)
Baseline Hematology, median (range)	
Neutrophil (10^9/L)	0.8 (0.1-8.6)
Hemoglobin (g/L)	69 (35-136)
Platelets (10^9/L)	43 (2-409)
Most common mutations	
DNMT3A	14 (24.6%)
ASXL1	12 (21.1%)
U2AF1	10 (17.5%)
RUNX1	9 (15.8%)

Data cut-off date: April 01, 2024

IMM01 Combined with AZA Showed Robust Response in Higher-risk MDS Patients

Best response rate, n (%)	ES N=51	≥4 months N=34	≥6 months N=29
CR	17 (33.3)	17 (50.0)	17 (58.6)
PR	0	0	0
mCR+HI	8 (15.7)	7 (20.6)	6 (20.7)
mCR	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)
NE(SD*)	3 (5.9)	0	0
PD	2 (3.9)	0	0
ORR (CR+PR+mCR+HI)	33 (64.7)	29 (85.3)	26 (89.7)
DCR (CR+PR+mCR+HI+SD)	45(88.2)	34 (100)	29 (100)



CR: complete response; PR: partial remission; mCR: marrow complete response; HI: Hematologic improvement; SD: stable disease; SD*:The SD not met for >8 weeks; PD: progressive disease; NE: not evaluable; ORR: overall response rate; DCR:disease control rate; ES (Evaluable analysis set): Defined as subjects with at least one post-baseline tumor assessment.

Data cut-off date: April 01, 2024

Duration of Response

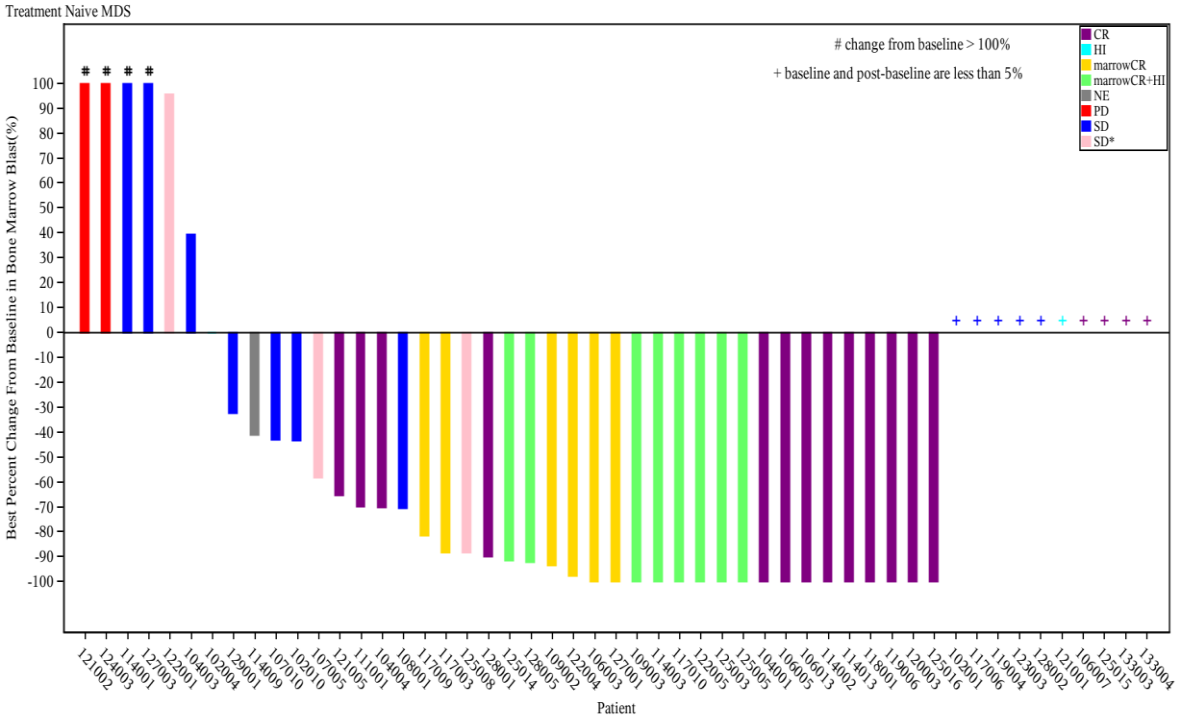


Figure 1. Waterfall plot for best percent change from baseline in the blast cells in the bone marrow

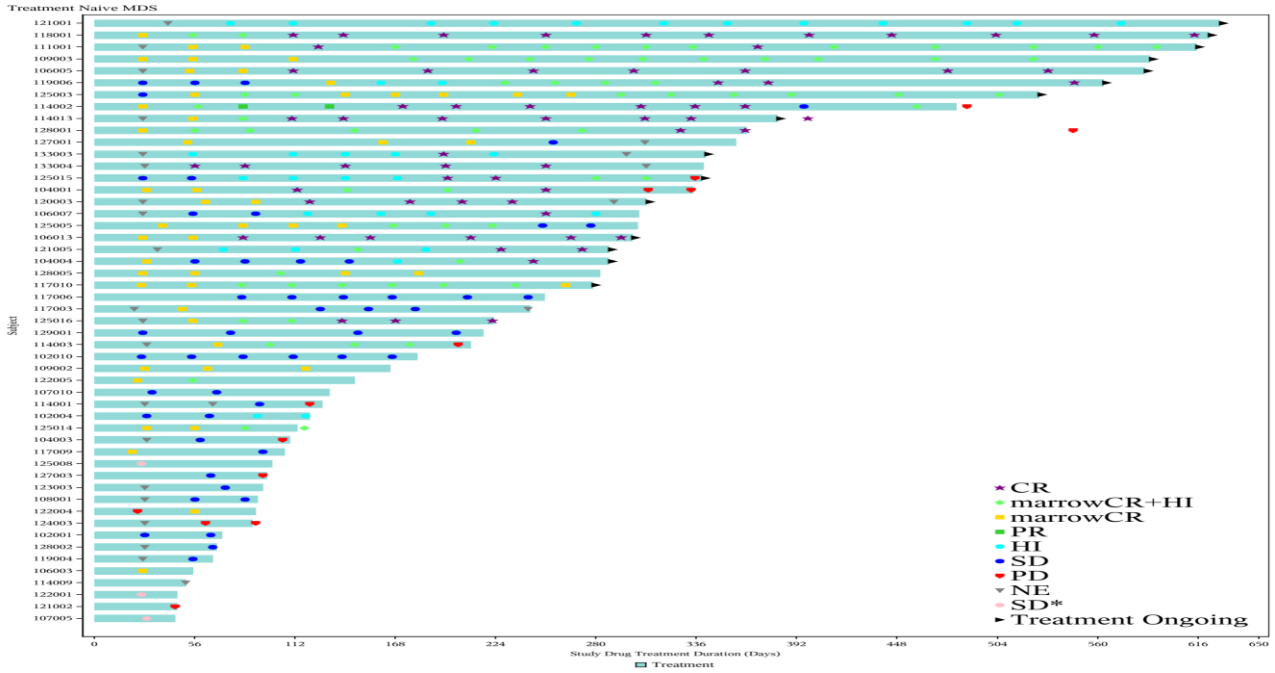


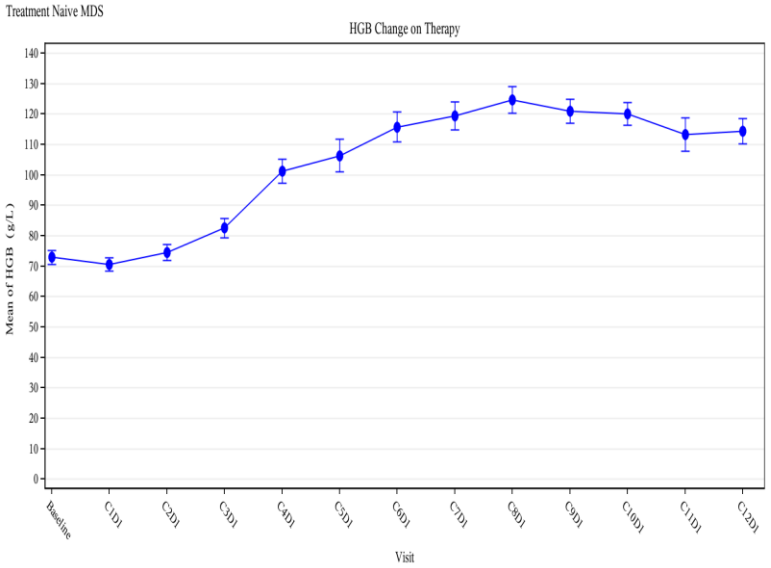
Figure 2. Swimmer plot for duration of treatment response

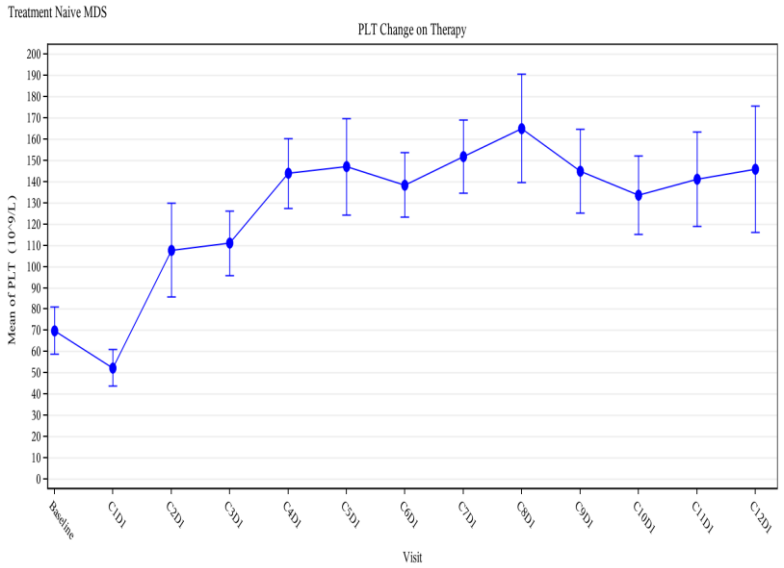
- Medium time to response (TTR) was 1.9 months.
- Median duration of response (DoR) was not reached.
- Medium duration of CR (DoCR) was not reached.

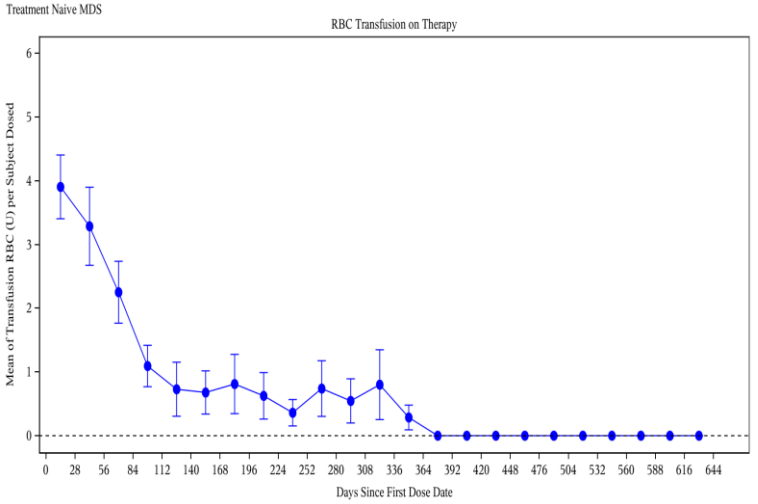
- Medium follow-up time was 15.9m
- The median of PFS、OS was not reached.
- The 12-month OS was 71.1 %.

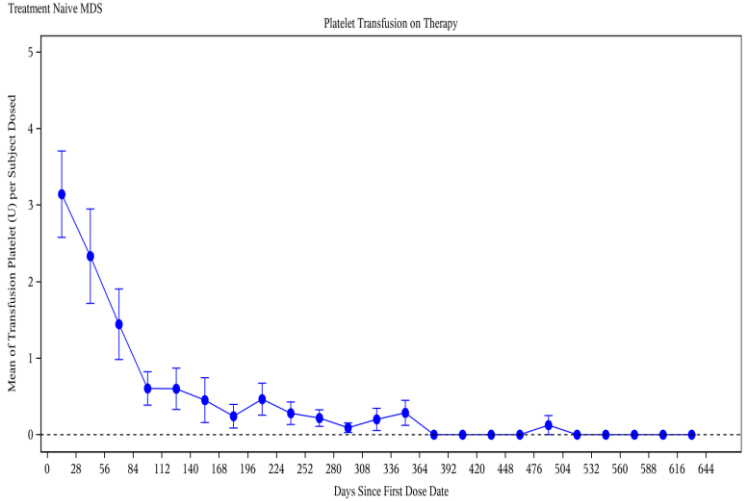
Data cut-off date: April 01, 2024

Improvement on HGB/PLT Levels and Transfusion









Postbaseline hematologic improvement	1L MDS (N =51)
Baseline hematological abnormalities	51/51 (100%)
Erythroid	19/49 (38.8%)
Platelet	19/42 (45.2%)
Neutrophil	7/32 (21.9%)

IMM01+AZA combination treatment led to the significant recoveries of HGB and PLT were observed, as well as the significant reduction in RBC or PLT transfusions.

Data cut-off date: April 01, 2024

Summary of TRAE

Overview of TRAE	1L MDS (N=57) n, (%)
All Grade TRAE	56 (98.2)
≥3TRAEs	52 (91.2)
TRAE leading to permanent discontinuation	3 (5.3)
Treatment-related of SAE	19 (33.3)

Hematologic conditions at baseline

- 70.2% of patients had Grade ≥ 3 anemia, 56.1% of patients had grade ≥3 thrombocytopenia, and 64.9% of patients had grade ≥3 neutropenia

Treatment-related adverse events

- By cut-off date of Apr 1, 2024, among 57 patients, 56 patients (98.2%) had TRAEs, 52 patients (91.2%) had Grade ≥3 TRAEs, the most common TREAs were hematological events.
- TRAEs leading to treatment discontinuation occurred in 3 patients (5.3%)
- Only 1 patient had Grade 3 hemolysis reported but resolved after treatment.

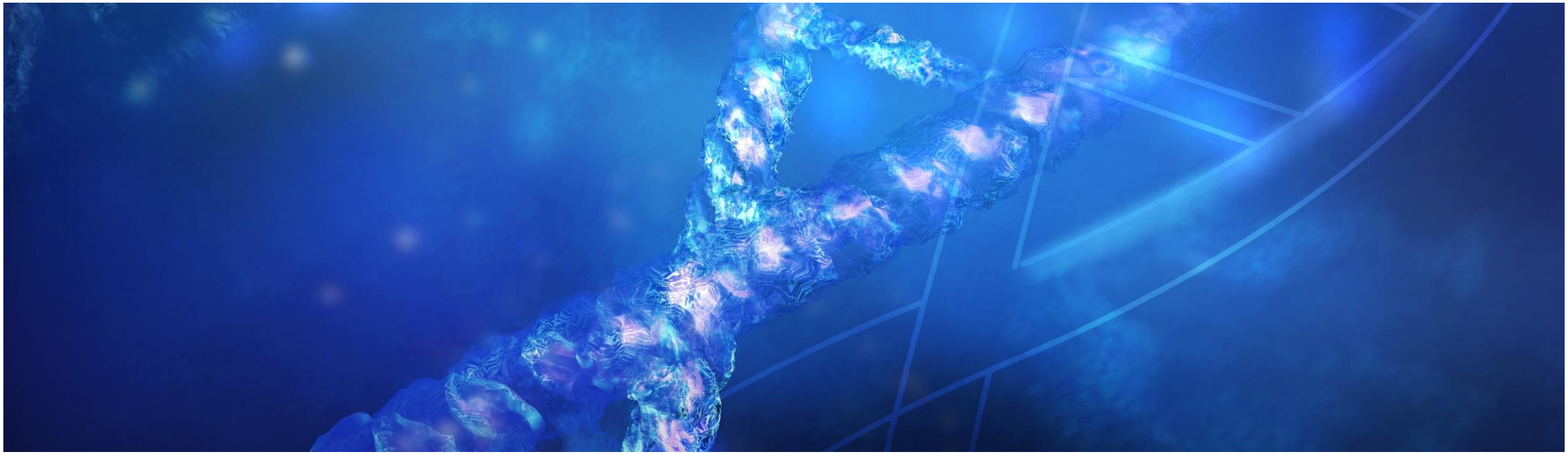
TRAE (≥ 20%)	1L MDS (N=57) n, (%)	
	All Grades	≥ G3
Leukopenia	47 (82.5)	45 (78.9)
Thrombocytopenia	41 (71.9)	38 (66.7)
Neutropenia	38 (66.7)	38 (66.7)
Lymphopenia	33 (57.9)	32 (56.1)
Anemia	27 (47.4)	25 (43.9)
Pyrexia	22 (38.6)	1 (1.8)
Infusion related reaction	19 (33.3)	2 (3.5)
Constipation	17 (29.8)	1 (1.8)
Vomiting	16 (28.1)	0
Hypoalbuminaemia	15 (26.3)	0
Nausea	13 (22.8)	0
Infection	13 (22.8)	10 (17.5)
Pneumonia	13 (22.8)	7 (12.3)

Data cut-off date: April 01, 2024

Conclusion

- Latest data showed that IMM01 (Timdarpacept) combined with AZA as the first-line treatment in adult patients with higher-risk MDS were well tolerated.
- IMM01 does not require priming dosing and no new safety signals emerged in combination with azacitidine.
- The combination of IMM01 and AZA demonstrated promising efficacy results in treatment-naïve higher-risk MDS patients. Among patients receiving treatment for ≥4 months, the ORR was 85.3%, with a CR rate of 50.1%. Among those receiving treatment for ≥6 months, the ORR increased to 89.7%, with a CR rate of 58.6%.
- The study is ongoing.

2 Latest Results of a Phase 2 Study of Timdarpacept (IMM01) in Combination with Tislelizumab in Prior Anti-PD-1 Failed Classical Hodgkin Lymphoma (cHL)



Background

- Anti-PD-1 mAb was approved for R/RcHL, with an ORR of 70% to 90%. However, most patients eventually relapse with a mPFS of 13-15 month, even for patients who achieved CR, more than half will progress within 2–3 years of starting treatment[1,2,3].
- There is no standard treatment for these patients who failed anti-PD-1 treatment.
- Novel therapies with Anti-PD-1 plus other immunotherapy provides future directions.

1. Armand, P., et al., J Clin Oncol. 2018
2. Kuruvilla, J, et al., Lancet Oncol. 2021
3. 2021 SOHO EXABS-110-NHL.

Study Design

- This is an open-label, multi-center, Phase II study of timdarpacept plus tislelizumab in anti-PD-1 failded R/R cHL.

Key criteria

- Diagnosed histologically with cHL
- Failed at least 2L prior systemic therapy (include anti-PD-1) or ASCT
- Measurable disease
- ECOG PS ≤ 1
- Adequate organ functions

Treatment

Timdarpacept:
2.0mg/kg IV QW

Tislelizumab:
200mg IV Q3W

Treatment until:

- Disease progression
- Unacceptable toxicity

Endpoints

Primary endpoint:

- ORR per Lugano 2014 criteria as assessed by investigator

Secondary endpoints:

- Safety
- ADA
- DoR, PFS, DCR, TTR

Demographics and Baseline Characteristics

Characteristic	N=33
Age, years	
Median (range)	35 (19-77)
Gender, n (%)	
Male	23 (69.7)
Female	10 (30.3)
ECOG PS, n (%)	
0	22 (66.7)
1	11 (33.3)
Ann Arbor Staging, n (%)	
II	1 (3.0)
III	10 (30.3)
IV	22 (66.7)
Bulky (≥10cm), n (%)	
Yes	2 (6.1)
No	31 (93.9)
Prior systemic anti-cancer therapy, n (%)	
Median (range)	4 (2-15)
2L	5 (15.2)
3L	10 (30.3)
4L	4 (12.1)
5L	5 (15.2)
≥5L	9 (27.3)

- 33 patients with R/R cHL were enrolled.
- The median lines of prior systemic anti-cancer therapy were 4.
- All patients previously received anti-PD-1 therapy.

Data cut-off date: March 01, 2024

Timdarpacept Combined with Tislelizumab Showed High Response in Anti-PD-1 Failed cHL Patients

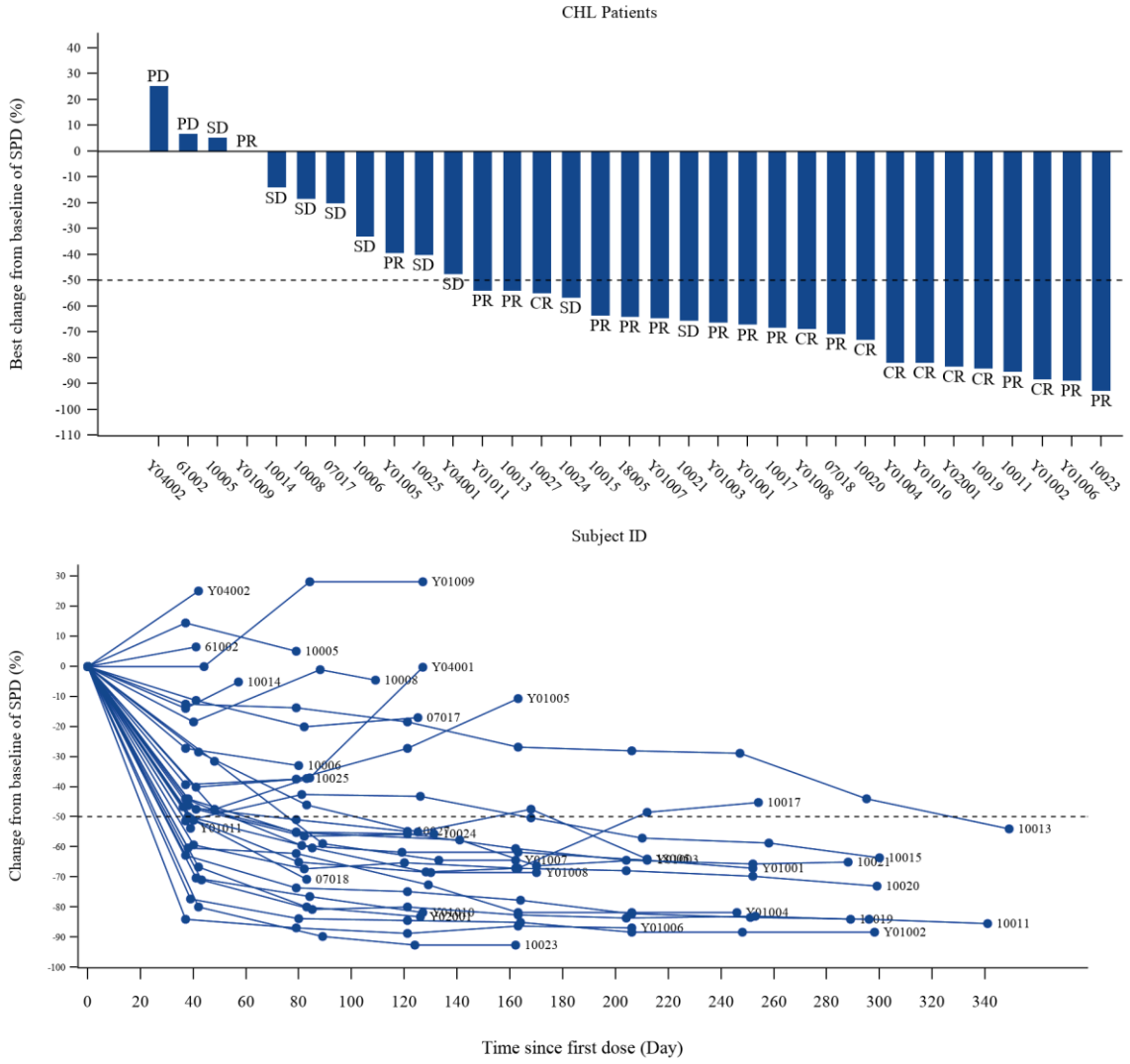
Best Response	N=33
CR, n (%)	8 (24.2)
PR, n (%)	14 (42.4)
SD, n (%)	9 (27.3)
PD, n (%)	2 (6.1)
ORR, n (%)	**22 (66.7)**
DCR, n (%)	**31 (93.9)**

Tumor Response by investigator:

- 33 patients were efficacy-evaluable.
- Best overall response rate was 66.7%, with 8 CR, 14 PR, 9 SD.

Data cut-off date: March 01, 2024

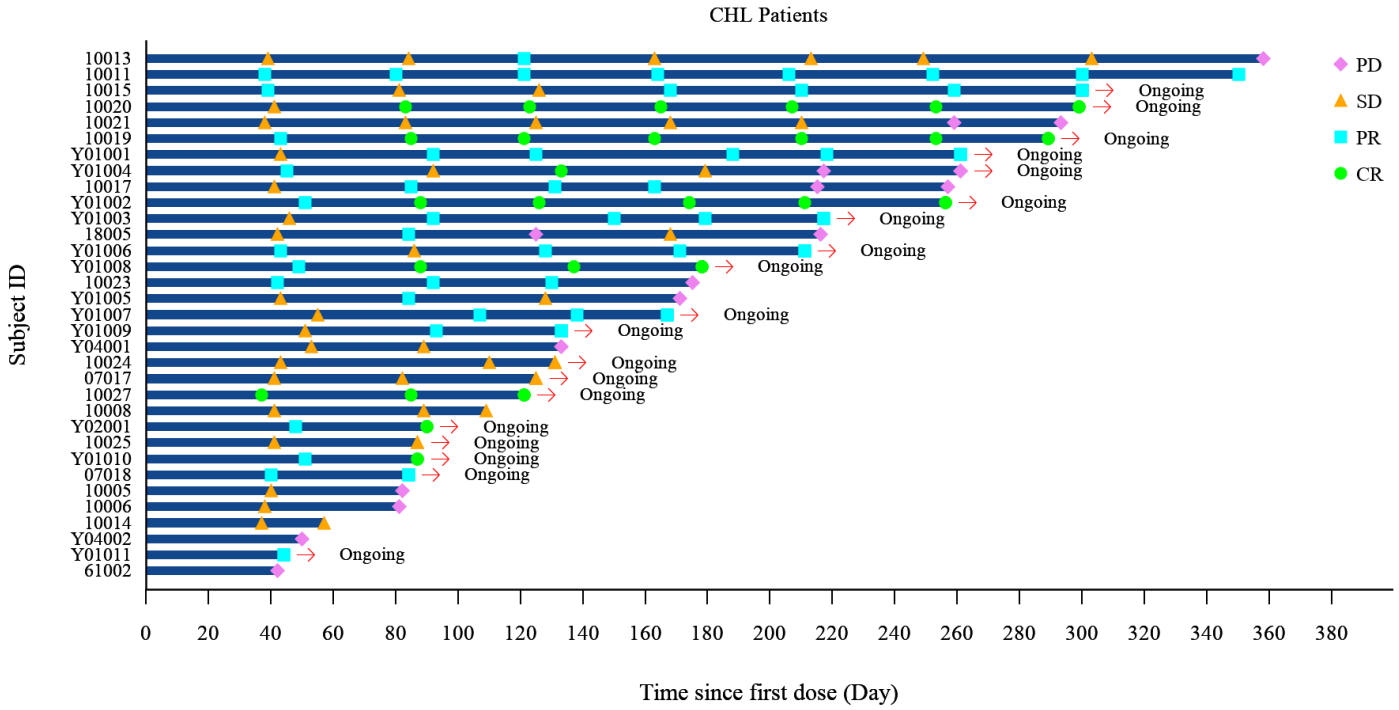
Tumor Size Change after Treatment



- 87.9% patients had target lesion size reduction.
- Two patients achieved PMR by PET-CT.

Data cut-off date: March 01, 2024

Duration of Response



With the median follow-up time of 6.87 months:

- Median progression-free survival (mPFS) was not reached.
- Median duration of response (mDOR) was not reached.

Data cut-off date: March 01, 2024

Summary of Safety Profile

Any grade TRAEs with incidence of ≥10%		
PT n(%)	Patients（n=33）	
	All Grades	G3-4
White blood cell count decreased	17 (51.5)	4 (12.1)
Platelet count decreased	14 (42.4)	4 (12.1)
Anemia	12 (36.4)	2 (6.1)
Neutrophil count decreased	12 (36.4)	4 (12.1)
Lymphocyte count decreased	10 (30.3)	10 (30.3)
Anti-erythrocyte antibody positive	9 (27.3)	0
Upper respiratory tract infection	7 (21.2)	1 (3.0)
Hepatic function abnormal	6 (18.2)	1 (3.0)
Infusion related reaction	5 (15.2)	0
Electrocardiogram ST-T change	5 (15.2)	0
Gamma-glutamyl transferase increased	4 (12.1)	0
Blood bilirubin increased	4 (12.1)	0
Fatigue	4 (12.1)	0
Prothrombin level increased	4 (12.1)	0
Sinus bradycardia	4 (12.1)	0

Overview of TRAE	N (%)
All grade TRAE	33 (100)
≥ G3 TRAE	15 (45.5)
TRAE leading to dose interruption	18 (54.5)
TRAE leading to permanent treatment discontinuation	0
Treatment-related SAE	4 (12.1)
TRAE leading to death	0
≥ G3 irAE	1 (3.0)

- 45.5% of patients had grade ≥3 TRAEs.
- No TRAEs led to death or permanent treatment discontinuation.
- 4 (12.1%) patients had treatment related SAE.
- The most common TRAEs were WBC decrease (51.5%), PLT decrease (42.4%), anemia (36.4%), neutropenia (36.4%) and lymphocytopenia (30.3%).
- No hemolysis events reported.

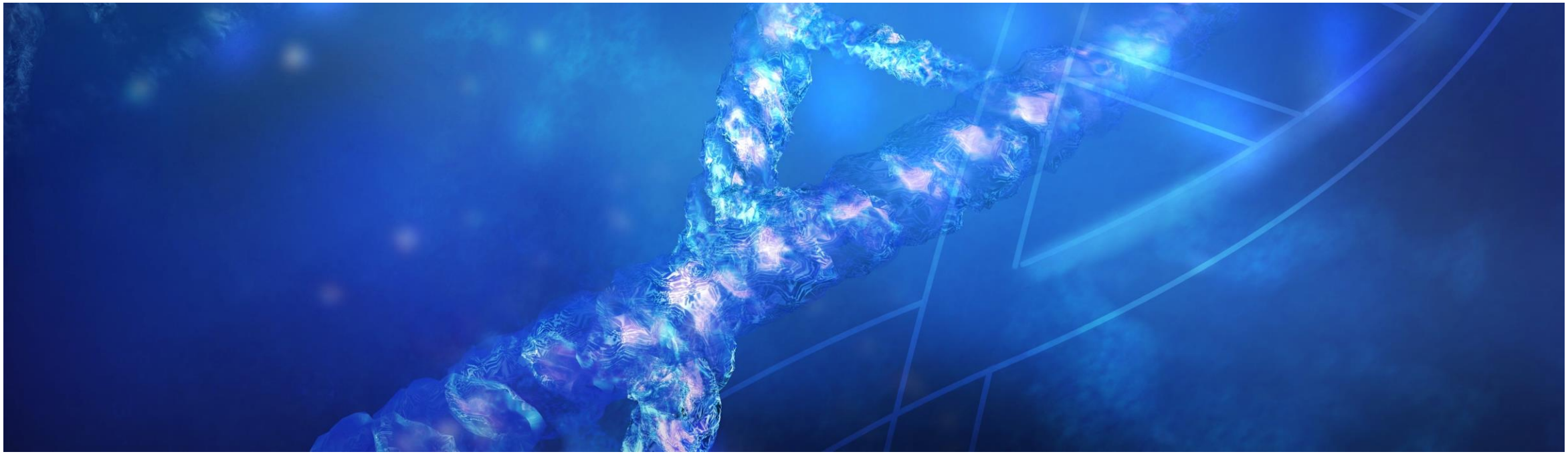
Data cut-off date: March 01, 2024

Conclusion

IMM01 (Timdarpacept) in combination with tislelizumab showed robust anti-tumor efficacy in anti-PD-1 failed cHL patients with acceptable safety profile:

- Remarkable anti-tumor efficacy:
  - ORR 66.7%, CR rate 24.2%.
  - mPFS was not reached.
- Safety:
  - Generally well tolerated, most common TRAEs were hematological events and clinically manageable.

3 IMM0306 (CD47xCD20) & IMM2510 (VEGFxPD-L1)



Poster Session and Publication

Preliminary results from a phase I study of IMM0306 in patients with relapsed orrefractory CD20-positive B-cell non-Hodgkin's lymphoma (ABSTRACT #442254)
Program Guide – ASCO Meeting Program Guide

Phase I safety and preliminary efficacy of IMM0306 in combination with lenalidomidein patients with relapsed or refractory CD20-positive B-cell non-Hodgkin'slymphoma (ABSTRACT #448190)
Program Guide – ASCO Meeting Program Guide

IMM2510, an anti-PD-L1/VEGF bispecific antibody fusion protein, in patients with advanced solid tumors: A phase I dose-escalation study (ABSTRACT #e14506)
Program Guide – ASCO Meeting Program Guide

Thank you

ImmuneOnco
Building 15, Zhangheng Road 1000
Pudong District
Shanghai, China
Email ir@immuneonco.com