IMC-002 (IMM0306), a First-in-Class CD20/CD47 Bispecific Fusion Protein, Demonstrates encouraging efficacy in Patients with Moderate to Severe Active Systemic Lupus Erythematosus (SLE) in the Open-label Phase 1b/2 Study

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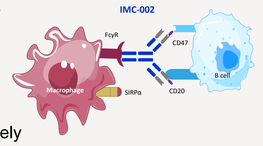
BACKGROUND

- IMC-002 (IMM0306) is a fusion protein of CD20 monoclonal antibody with an engineered SIRPα domain on both heavy chains.
- IMC-002 possesses:
  - Stronger ADCC/ADCP activity compared to rituximab;
  - No in vitro binding to human RBC;
  - CD47 is highly expressed in all B cell subsets, while CD20 is barely expressed in plasmablasts.



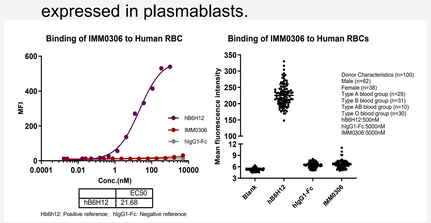


Figure 1. IMC-002 is In Vitro Safe to Red Blood Cells (RBC)

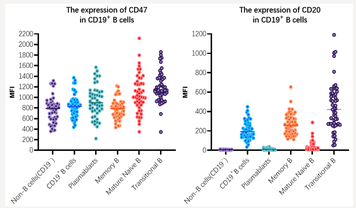


Figure 2. Expression Results of CD47/CD20 in B cell Subsets in Autoimmune Patients

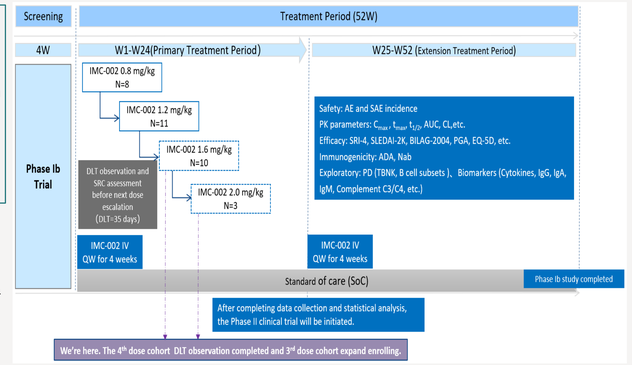
METHODS

Phase 1b Trial Design (Multicenter, Open-label, Dose-escalation Study) _NCT06535412

Key Enrollment Criteria

- Diagnosis of SLE ≥ 12 weeks prior to screening in accordance with 2019 EULAR/ACR SLE classification criteria for Moderate to Severe Active SLE ;
- SLEDAI-2K ≥ 6;
- BILAG-2004 ≥ 1A or ≥ 2B;
- ANA or Anti-dsDNA positive.

SLE: Systemic lupus erythematosus
EULAR: The European Alliance of Associations for Rheumatology
ACR: American College of Rheumatology
SRI-4： Systemic Lupus Erythematosus Responder Index
SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000.
BILAG-2004: British Isles Lupus Assessment Group Index
PGA : Physician Global Assessment
dsDNA: double-stranded DNA
DLT: Dose Limiting Toxicity



Summary

- ✓ There is no dose-limiting toxicities (DLTs) observed at any dose level.
- ✓ IMC-002 demonstrated favorable safety profile across the 0.8 mg/kg to 1.6 mg/kg dose cohorts. Majority of TEAE were mild, and the most common G3 TEAE was platelet decrease (4/32, 12.5%) and recovered spontaneously without clinical sequalae. No cytokine release syndrome (CRS), and no significant infectious events were observed.
- ✓ Robust efficacy was observed, with SRI-4 response rates at Week 24 of 71.4% (0.8 mg/kg), 72.7% (1.2 mg/kg), and 80.0% (1.6 mg/kg). The response was durable and retained through Week 52. It is premature for 2.0 mg/kg dose level to evaluate efficacy until data cut off.
- ✓ IMC-002 induced rapid and complete peripheral CD19+ B cell depletion (<5 cells/μL) in all patients after the first four doses, followed by B cell reset starting in around 8 weeks post first dose but sustained plasmablast suppression. Immunoglobulin levels remained within normal range. IL 6 increased at first dose but without clinical CRS occurred and remained at low level afterwards.
- ✓ Based on a favorable benefit-risk profile, 1.2 mg/kg and 1.6 mg/kg were selected as the recommended Phase 2 doses (RP2Ds) to be further evaluated in a randomized, double-blinded, placebo-controlled Phase 2 study which has been initiated in Apr 2026.

RESULTS

Table 1. Baseline Characteristics of participants from phase 1b study

	IMC-002				
	0.8mg/kg (N=8)	1.2mg/kg (N=11)	1.6mg/kg (N=10)	2.0mg/kg (N=3)	Total (N=32)
Female, n (%)	6 (75.0)	10 (90.9)	9 (90.0)	3 (100.0)	28 (87.5)
Age (years), median (min, max)	40 (26, 63)	32 (19, 49)	35 (26, 62)	42 (29, 44)	34.5 (19, 63)
SLEDAI-2K, mean (min, max)	10.5 (7, 16)	12.5 (8, 22)	12.7 (6, 18)	10.7 (8, 16)	11.9 (6, 22)
BILAG-2004 organ domain involvement, n (%)					
2A or 1A	1(12.5)	2(18.2)	4(40.0)	1(33.3)	8(25.0)
2B	7(87.5)	9(81.8)	6(60.0)	2(66.7)	24(75)
PGA, mean (SD)	1.71 (0.445)	1.68 (0.397)	1.92 (0.466)	1.53 (0.231)	1.75 (0.422)
IgG(g/L), mean (SD)	12.9 (5.0)	13.5 (3.0)	13.0(2.2)	12.2 (8.0)	13.0 (3.8)
Proteinuria > 0.5 g/24h at baseline , n (%)	3 (37.5)	4 (36.4)	3 (30.0)	2 (66.7)	12 (37.5)
BILAG-2004 domain A or B score, n (%)					
Constitutional	0	0	1(10.0)	0	1(3.1)
Mucocutaneous	6(75.0)	8(72.7)	5(50.0)	2(66.7)	21(65.6)
Musculoskeletal	4(50.0)	7(63.6)	6(60.0)	1(33.3)	18(56.3)
Renal	6(75.0)	6(54.6)	5(50.0)	2(66.7)	19(59.4)
Cardiorespiratory	0	0	0	1(33.3)	1(3.1)

Table 2. Safety Summary

Overview of TRAEs , n (%)	IMC-002				
	0.8mg/kg (N=8)	1.2mg/kg (N=11)	1.6mg/kg (N=10)	2.0mg/kg (N=3)	Total (N=32)
All grade TRAE	4 (50)	7 (63.6)	8 (80)	3 (100)	22 (68.8)
≥ G3 TRAE	1 (12.5)	1 (9.1)	0	3 (100)	5 (15.6)
TRAE leading to dose reduction	0	0	0	0	0
Treatment-related SAE	0	0	0	0	0
TRAE leading to withdrawal	0	0	0	0	0
TRAE leading to death	0	0	0	0	0

Table 3. Summary of TEAEs (≥ 10% in total) by PT

PT, n (%)	IMC-002				
	0.8mg/kg (N=8)	1.2mg/kg (N=11)	1.6mg/kg (N=10)	2.0mg/kg (N=3)	Total (N=32)
Platelet count decreased	3 (37.5)	1 (9.1)	2 (20.0)	3 (100.0)	9 (28.1)
Upper respiratory tract infection	1 (12.5)	3 (27.3)	3 (30.0)	2 (66.7)	9 (28.1)
Anaemia	1 (12.5)	3 (27.3)	4 (40.0)	1 (33.3)	9 (28.1)
Infusion-related reaction	1 (12.5)	3 (27.3)	2 (20.0)	1 (33.3)	7 (21.9)
Alanine aminotransferase increased	1 (12.5)	4 (36.4)	0	1 (33.3)	6 (18.8)
Neutrophil count increased	1 (12.5)	4 (36.4)	1 (10.0)	0	6 (18.8)
Weight gain	1 (12.5)	2 (18.2)	1 (10.0)	1 (33.3)	5 (15.6)
Aspartate aminotransferase increased	1 (12.5)	4 (36.4)	0	0	5 (15.6)
White blood cell count increased	2 (25.0)	3 (27.3)	0	0	5 (15.6)
White blood cell count decreased	0	2 (18.2)	2 (20.0)	1 (33.3)	5 (15.6)
Hypertriglyceridaemia	0	1 (9.1)	4 (40.0)	0	5 (15.6)
Gamma-glutamyltransferase increased	1 (12.5)	1 (9.1)	1 (10.0)	1 (33.3)	4 (12.5)
Bacteria test positive	1 (12.5)	0	3 (30.0)	0	4 (12.5)
Hypoalbuminaemia	0	2 (18.2)	1 (10.0)	1 (33.3)	4 (12.5)
Hyperuricaemia	1 (12.5)	3 (27.3)	0	0	4 (12.5)

Table 4. Summary of TEAEs Grade ≥3 in Severity by PT

PT, n (%)	IMC-002				
	0.8mg/kg (N=8)	1.2mg/kg (N=11)	1.6mg/kg (N=10)	2.0mg/kg (N=3)	Total (N=32)
Platelet count decreased	1 (12.5)	1 (9.1)	0	2 (66.7)	4 (12.5)
Headache	2 (25.0)	0	0	0	2 (6.3)
White blood cell count decreased	0	0	0	1 (33.3)	1 (3.1)
Anaemia	0	0	0	1 (33.3)	1 (3.1)

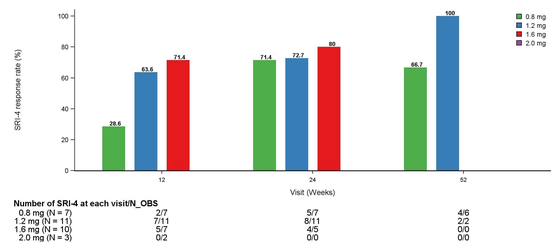


Figure 3. Achieved SRI-4 Response

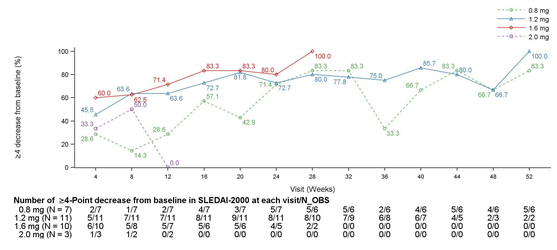


Figure 4. SLEDAI-2K reduction ≥ 4

Note:

- N_OBS = number of participants in each group who completed the corresponding visit;
- 1 patient without post-baseline efficacy assessment was not included in the 0.8 mg/kg dose cohort.

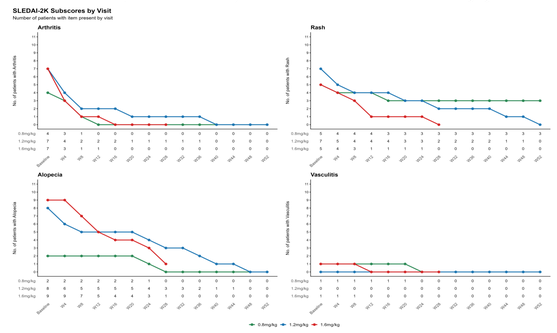


Figure 5. The Symptom (Arthritis, Rash, Alopecia, Vasculitis) Disappeared in SLEDAI-2K

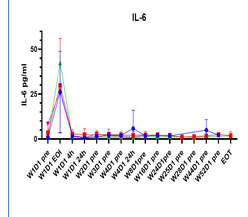


Figure 6. IL-6 Level

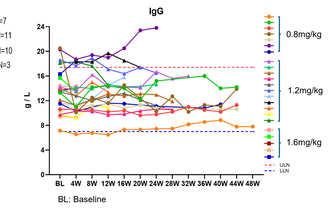


Figure 7. IgG Level

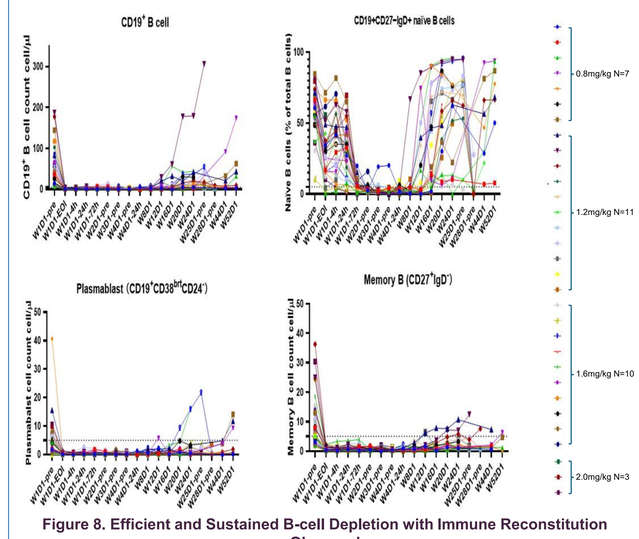


Figure 8. Efficient and Sustained B-cell Depletion with Immune Reconstitution Observed

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- **Data cut-off Mar 5th, 2026**