

Abstract #2464: IMC-002 (IMM0306), a First-in-Class Bispecific Fusion Protein, Demonstrates Improvements in SLE Disease Activity Measures and Biomarkers 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 was highly expressed in all B cell subsets, CD20 is almost not expressed in plasmablasts.

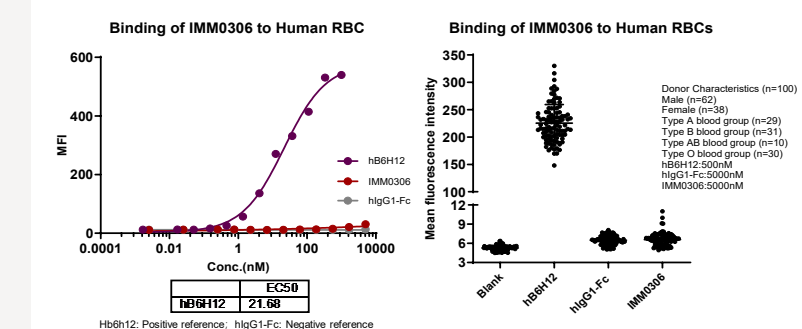


Figure 1. IMC-002 is In Vitro Safe to Red Blood Cells (RBC)

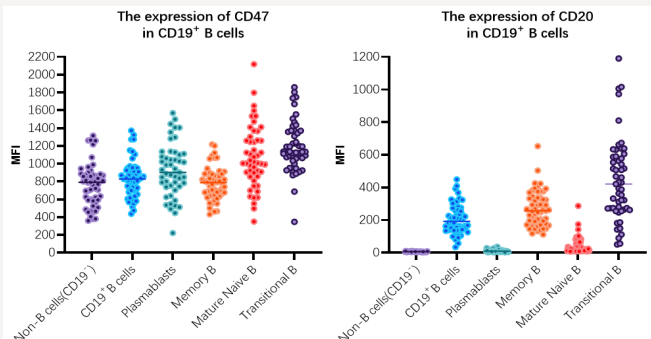
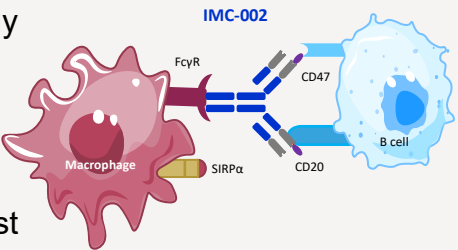


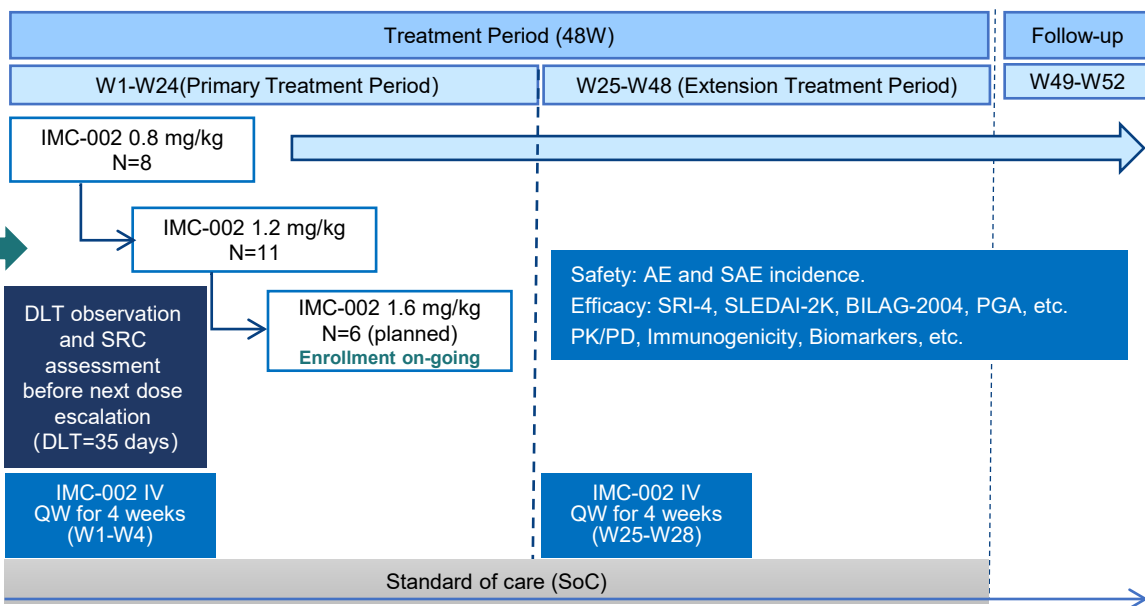
Figure 2. Expression Results of CD47/CD20 in B cell Subsets in Autoimmune Patients

METHODS

Phase Ib 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



RESULTS

Table 1. Baseline Characteristics of subjects from phase Ib study

	IMC-002		Total (N=19*)
	0.8mg/kg (N=8*)	1.2mg/kg (N=11)	
Female, n (%)	6 (75)	10(90.9)	16(84.3)
Age (years), median (min, max)	39.5(26, 63)	32(19, 49)	34(19, 63)
SLEDAI-2K, mean (min, max)	10.75 (7, 16)	12.55(8, 22)	11.79(7, 22)
BILAG-2004 organ domain involvement, n (%)			
2A or 1A	1 (12.5)	2(18.2)	3(15.8)
2B	7 (87.5)	9(81.8)	16(84.2)
PGA, mean (SD)	1.71 (0.45)	1.68(0.40)	1.69(0.41)
IgG(g/L), mean (SD)	12.89(4.95)	13.34(3.15)	13.14(3.92)
Organ-involvement, n (%)			
Skin, n (%)	6 (75)	8(72.7)	14(73.7)
Joint, n (%)	4 (50)	7(63.6)	11(57.9)
Renal, n (%)	4 (50)	6(54.5)	10(52.6)
Hematology, n (%)	3 (37.5)	3(27.3)	6(31.6)

*: Including one subject who received only one dose
SD, standard deviation

Table 2. Safety Summary

Overview of TRAEs, n(%)	IMC-002		Total (N=19*)
	0.8mg/kg (N=8*)	1.2mg/kg (N=11)	
All grade TRAE	5(62.5)	9(81.8)	14(73.7)
≥ G3 TRAE	1(12.5)	1(9.1)	2(10.5)
TRAE leading to dose reduction	0	0	0
Treatment-related SAE	0	0	0
TRAE leading to interruption**	1(12.5)	3(27.3)	4(21.1)
TRAE leading to withdrawal	0	0	0
TRAE leading to death	0	0	0

*: Including one subject who received only one dose
**:3 patients experienced infusion reaction, 1 patient experienced allergic reaction

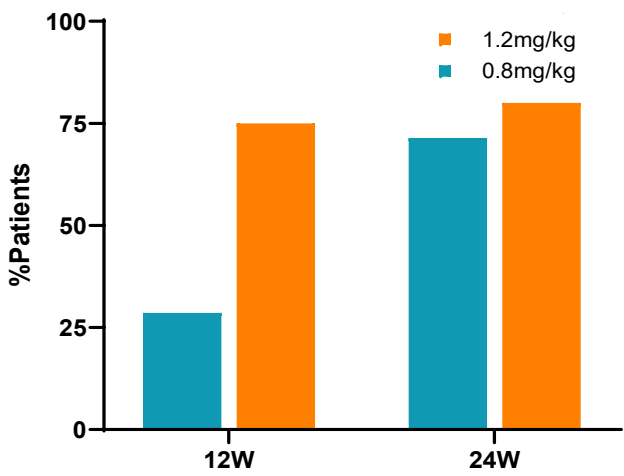


Figure 5. Achieved SRI-4 Response

12W: 7 patients in 0.8m/kg cohort, 8 patients in 1.2m/kg cohort
24W: 7 patients in 0.8m/kg cohort, 5 patients in 1.2m/kg cohort

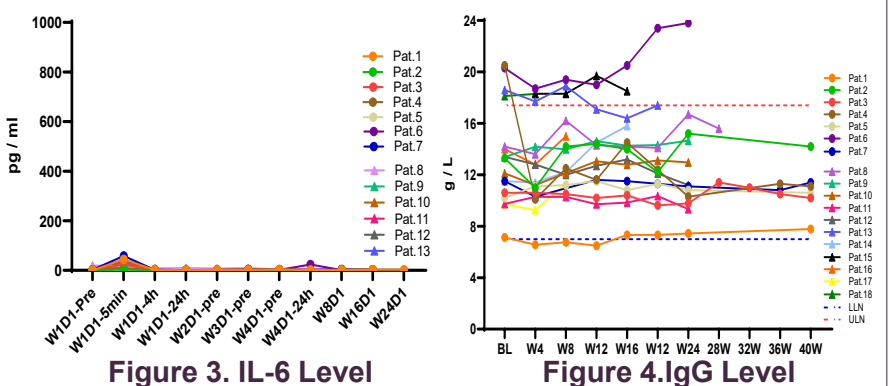


Figure 3. IL-6 Level

BL: Baseline
0.8 mg/kg Cohort: Pat.1-7; 1.2 mg/kg Cohort: Pat.8-18

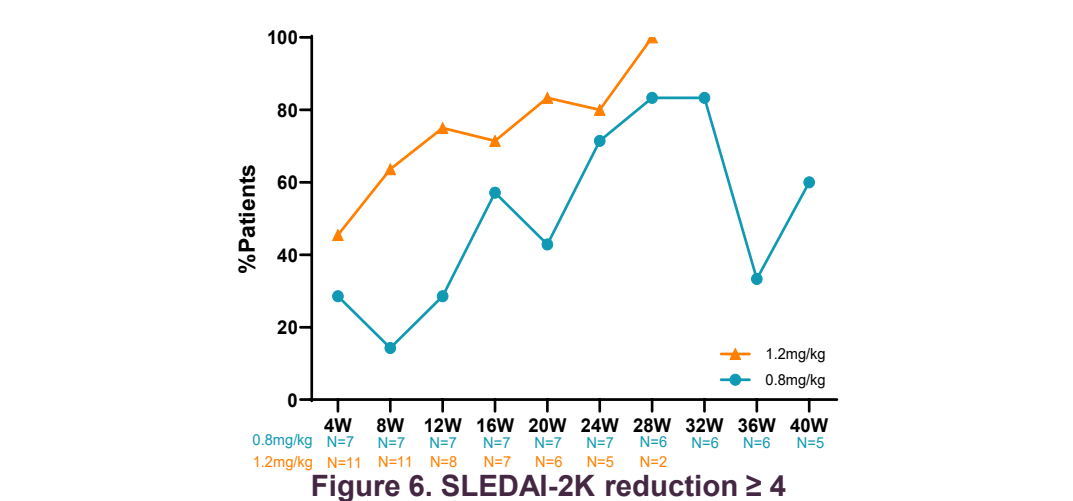


Figure 6. SLEDAI-2K reduction ≥ 4

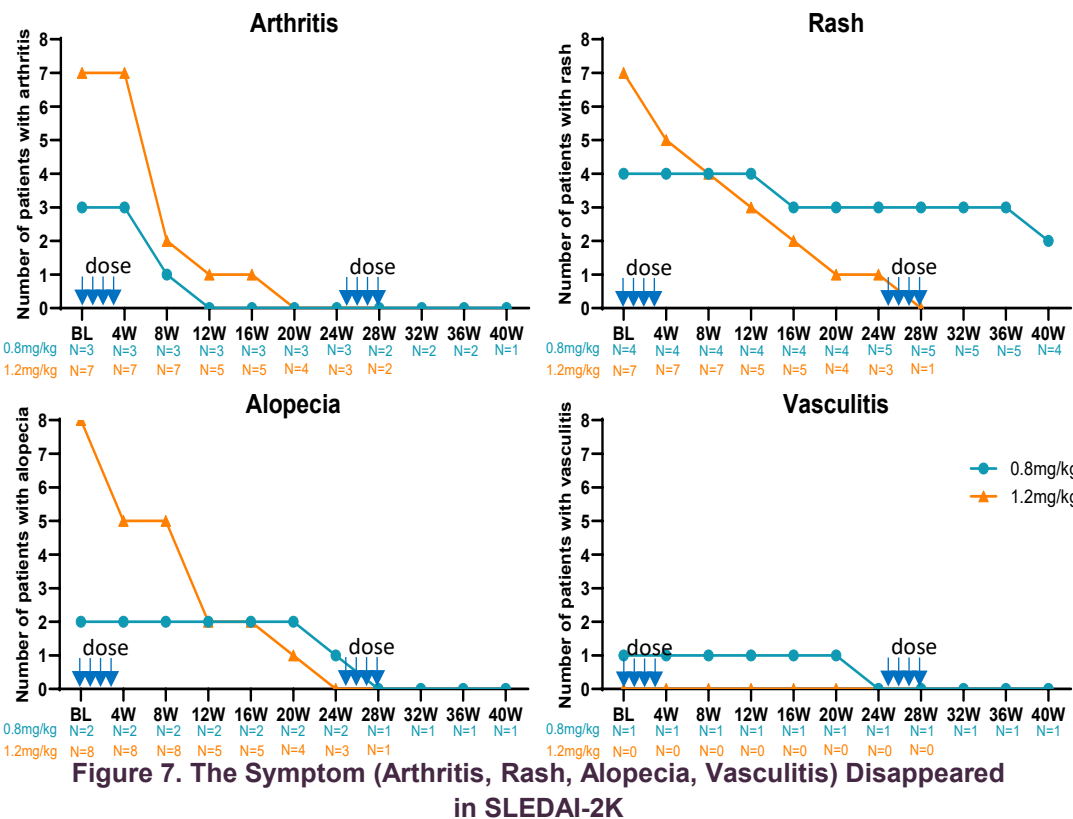


Figure 7. The Symptom (Arthritis, Rash, Alopecia, Vasculitis) Disappeared in SLEDAI-2K

Summary

- Both the IMC-002 0.8 mg/kg and 1.2 mg/kg cohorts demonstrated favourable safety and tolerability, with no occurrence of DLT events, no Cytokine Release Syndrome (CRS), or significant infectious events. The immunoglobulin levels were within the normal range.
- The SRI-4 rates at 24W for the 0.8 mg/kg and 1.2 mg/kg cohorts were 71.4% (5/7) and 80.0% (4/5) respectively. 6 patients in 1.2 mg/kg cohort still not reached the 24W evaluation.
- Anti-dsDNA antibody, 24-hour urine protein, and complement C3/C4 all showed significant improvement trends.
- Deep B-cell-depletion in the both cohorts demonstrated the potential for treating B-cell-driven autoimmune diseases. 5 Patients observed B-lineage cells reconstruction between 12-24W.

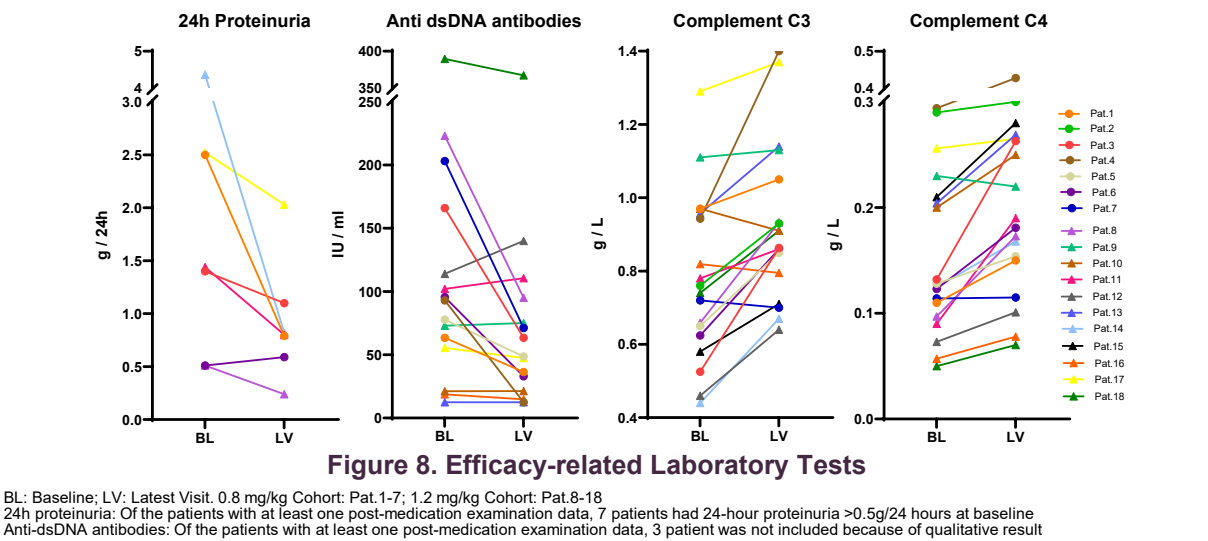


Figure 8. Efficacy-related Laboratory Tests

BL: Baseline; LV: Latest Visit. 0.8 mg/kg Cohort: Pat.1-7; 1.2 mg/kg Cohort: Pat.8-18
24h proteinuria: Of the patients with at least one post-medication examination data, 7 patients had 24-hour proteinuria >0.5g/24 hours at baseline
Anti-dsDNA antibodies: Of the patients with at least one post-medication examination data, 3 patient was not included because of qualitative result

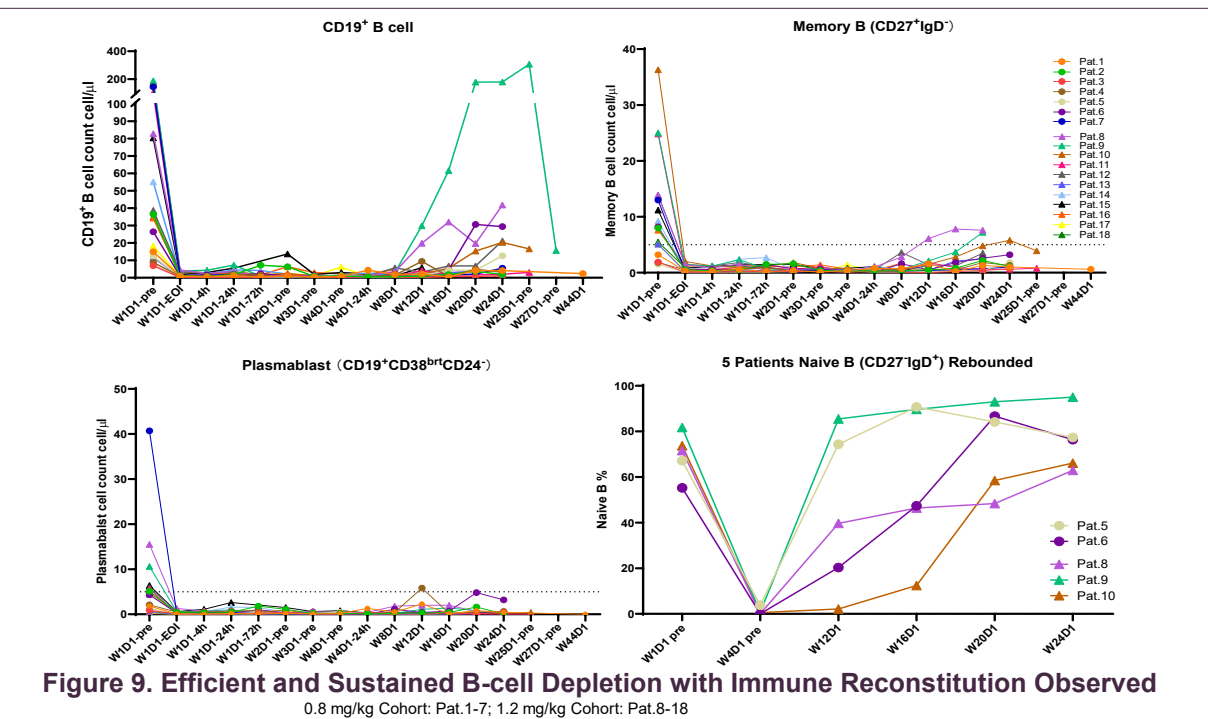


Figure 9. Efficient and Sustained B-cell Depletion with Immune Reconstitution Observed

0.8 mg/kg Cohort: Pat.1-7; 1.2 mg/kg Cohort: Pat.8-18

• Data cut-off Sep 10, 2025