Amulirafusp alfa (IMM0306)
- First-in-Class CD47×CD20 Bispecific Antibody for SLE
- Preliminary Phase I Results

ImmuneOnco (01541.HK)

BIO International Convention

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Amulirafusp Alfa (IMM0306) - A Novel CD47xCD20 Bispecific Antibody with Best-in-disease Potential in SLE

Dual targeting of CD47 and CD20

- Engineered IgG1 Fc
- Strong ADCC/ADCP
- Safe to RBC in vitro

First-in-class for autoimmune diseases

- Rapid, efficient and sustained B-cell depletion
- Immune reconstitution with lower risk of infection

Best-in-disease potential

- 83.3% response in SLEDAI-2K at 1.2 mg/kg [1]
- No CRS
- Improvement in multiple measurements

Multiple indications in development

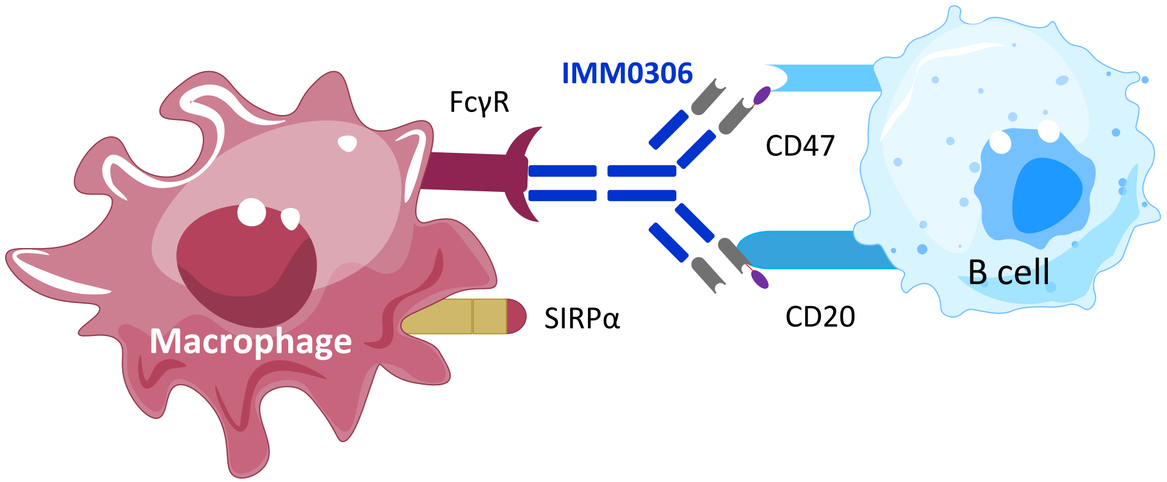
- Phase II in follicular lymphoma ongoing: CRR 64.7%
- Approved IND
  - China: SLE, LN, NMOSD, NHL
  - USA: NHL

1. Defined as the percentage of patients (SLEDAI-2K ≥8) achieving ≥4-point reduction from baseline.

ADCP: Antibody-dependent cellular phagocytosis; ADCC: Antibody dependent cell-mediated cytotoxicity. RBC: red blood cell;

CRR: complete response rate; SLE: systemic lupus erythematosus; NMOSD: neuromyelitis optica spectrum disorder; LN: Lupus nephritis; NHL: Non-Hodgkin lymphoma

Mechanism of Action - Amulirafusp alfa (IMM0306)

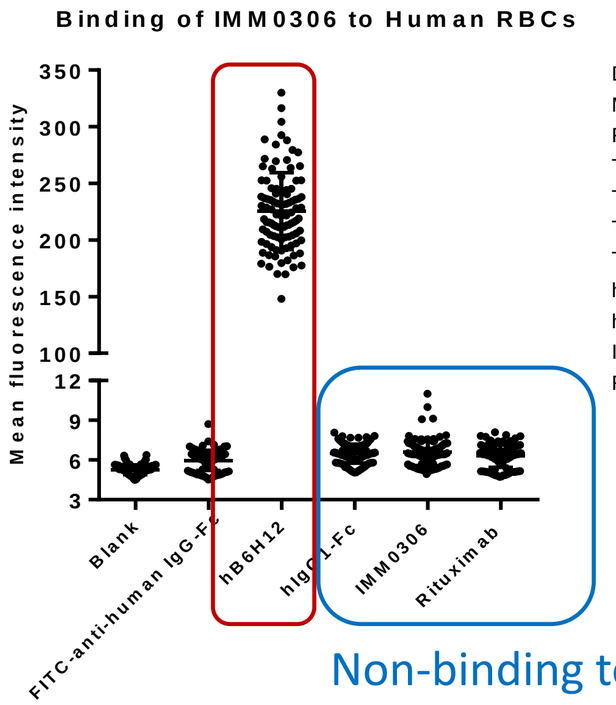


- IMM0306 is a **fusion protein of CD20 mAb with the CD47 binding domain of SIRPα** on both heavy chains.
- IMM0306 possesses:
  - **Stronger ADCC/ADCP activity compared to rituximab**
  - **No in vitro binding to human RBC**
  - **Higher affinity to CD20 better avoid normal cell killing**

ADCP: Antibody-dependent cellular phagocytosis; ADCC: Antibody dependent cell-mediated cytotoxicity.

Amulirafusp alfa (IMM0306) is In Vitro Safe to Red Blood Cells (RBC)

In vitro binding assay to RBC



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
hIgG1-Fc:5000nM
IMM0306:5000nM
Rituximab:5000nM

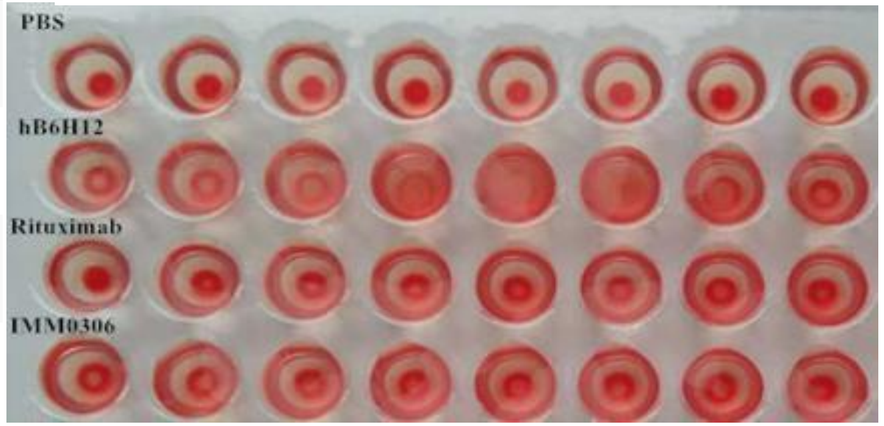
Non-binding to human RBC

Hemagglutination assay

	Hemagglutination
PBS (negative control)	No
hB6H12 (positive control)	Yes
Rituximab	No
IMM0306	**No**

Concentration (nM)

4000 1333 444 148 49.4 16.5 5.49 1.83



IMM0306 is Efficacious as Monotherapy, in Combo with Lenalidomide and to anti-CD20-treated Lymphoma Patients

	Phase I	Phase II	Patients with prior anti-CD20 treatment (obinutuzumab)
Treatment	Monotherapy[1]	Combined with Lenalidomide[2]	Combined with Lenalidomide[2]
	Follicular lymphoma (n = 17)	Follicular lymphoma (n = 34)	n = 10
CR	**4 (23.5%)**	**22 (64.7%)**	**5 (50%)**
PR	**3 (17.6%)**	**8 (23.5%)**	**3 (30%)**
SD	4 (23.5%)	2 (5.9%)	1 (10%)
PD	6 (35.3%)	2 (5.9%)	0
ORR	**7 (41.2%)**	**30 (88.2%)**	**8 (80%)**
DCR	11 (64.7%)	32 (94.1%)	9 (90%)

1. IMM0306 monotherapy data is as of April 18, 2024, among 17 efficacy evaluable patients with r/r FL who received doses 0.8-2.0 mg/kg. 2. Cut off date as June 9, 2025

Significant Unmet Needs Among Systemic Lupus Erythematosus (SLE) Patients

3.4 million

Global SLE population[1]

10th leading cause of death

in females 15-24 yr, USA[2]

400 k/yr

Newly diagnosed SLE patients[1]

Top 20 leading cause of death

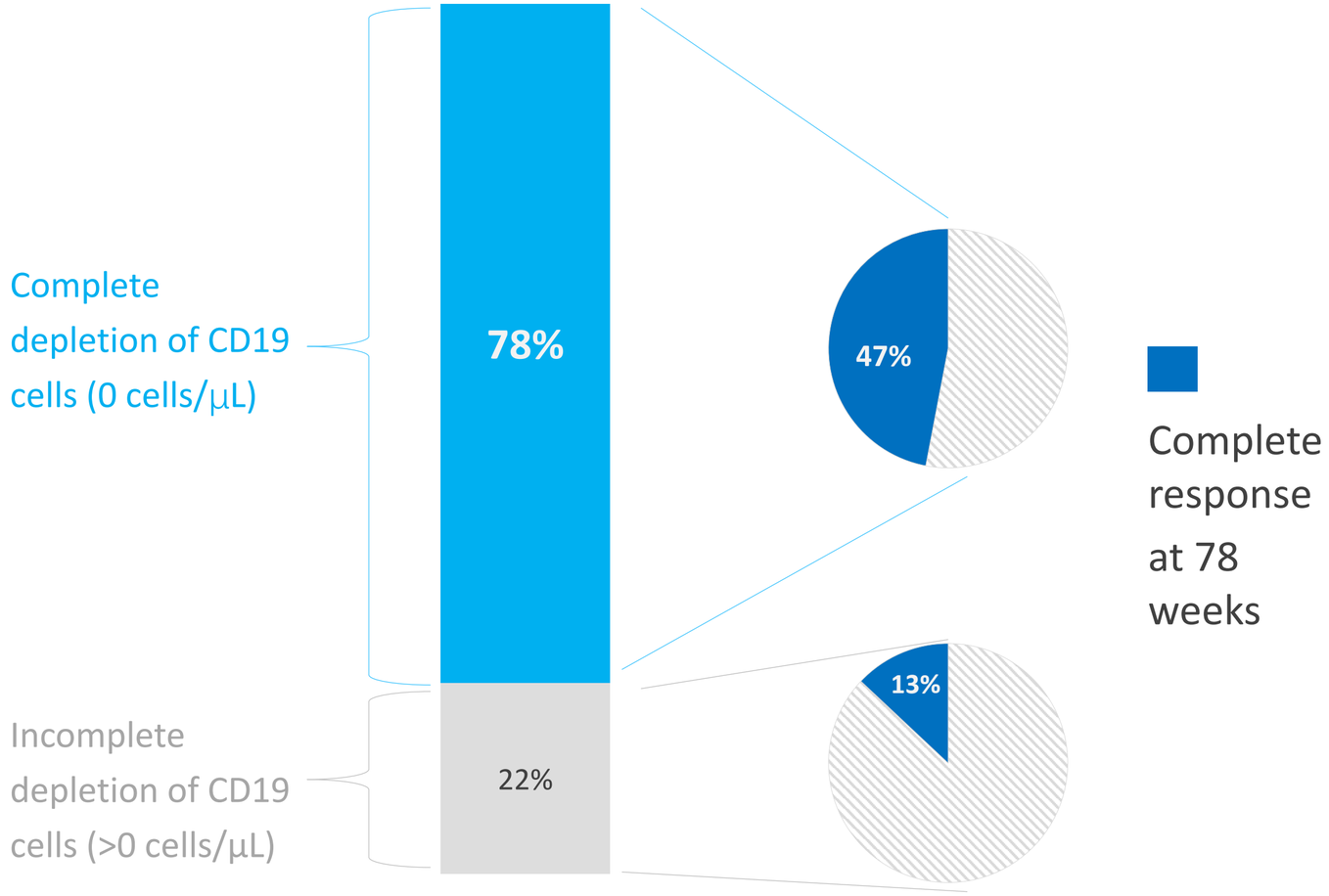
in females 5-64 yr, USA[2]

1. Tian et al. Ann Rheum Dis. 2023 Mar;82(3):351-356. 2. Yen et al. Arthritis Rheumatol. 2018 Aug;70(8):1251-1255.

Enhancing B-Cell Depletion for Greater Efficacy

"Although the B cell depletion agent rituximab failed to reach its primary end points in randomized controlled trials in systemic lupus erythematosus (SLE), favorable clinical experience has led to its frequent off-label use in patients with SLE."[1]

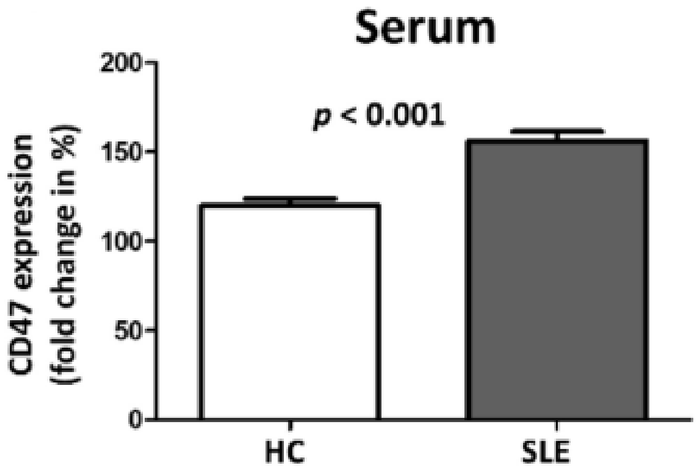
Percentage of patients in LUNAR study - anti-CD20 rituximab in lupus nephritis[2]



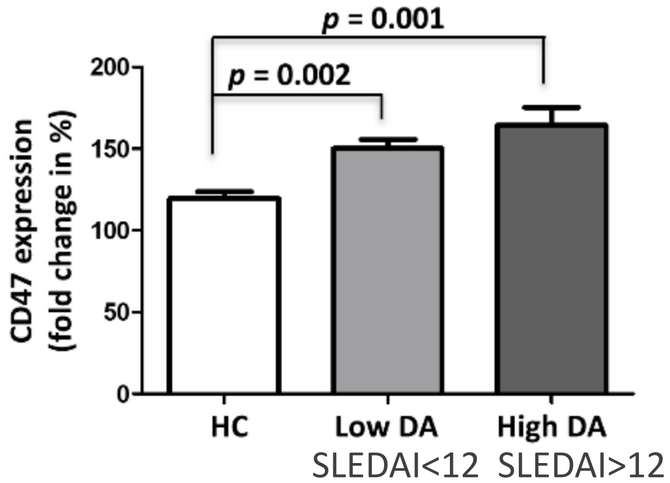
1. Stockfelt et al. Nat Rev Rheumatol. 2025 Feb;21(2):111-126. 2. Mendez et al. Clin J Am Soc Nephrol. 2018 Aug 8;13(10):1502–1509.

CD47 Expression Links to SLE Disease Activity and IFN-α Upregulation

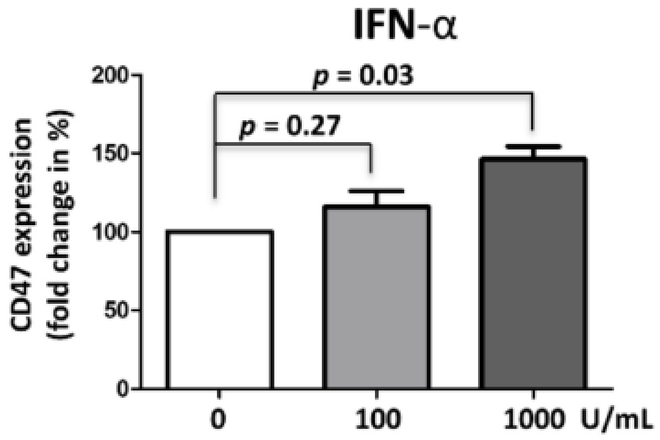
Upregulation of CD47 by SLE serum



Subgroup analysis



Expression of CD47 at presence of IFN-α



- Elevated CD47 expression makes it a promising therapeutic target for SLE.

Park et al. Cells. 2021 May 10;10(5):1151. HC: Healthy control serum; DA: disease activity.

Left: Healthy PBMCs were incubated with serum from healthy controls (HC, n = 6) and SLE patients (n = 10), and fold changes in CD47 expression on monocytes were investigated by flow cytometry analysis.

Middle: Effect of serum from patients with low (n = 6) and high (n = 4) disease activity on CD47 expression was examined.

Right: Healthy PBMCs (n = 3) were incubated with increasing concentrations of interferon-alpha (IFN-α) and change in CD47 expression was examined by flow cytometry. Untreated samples served as a reference (i.e., 100%).

Enhanced B-Cell Depletion in CD47-Deficient Mice

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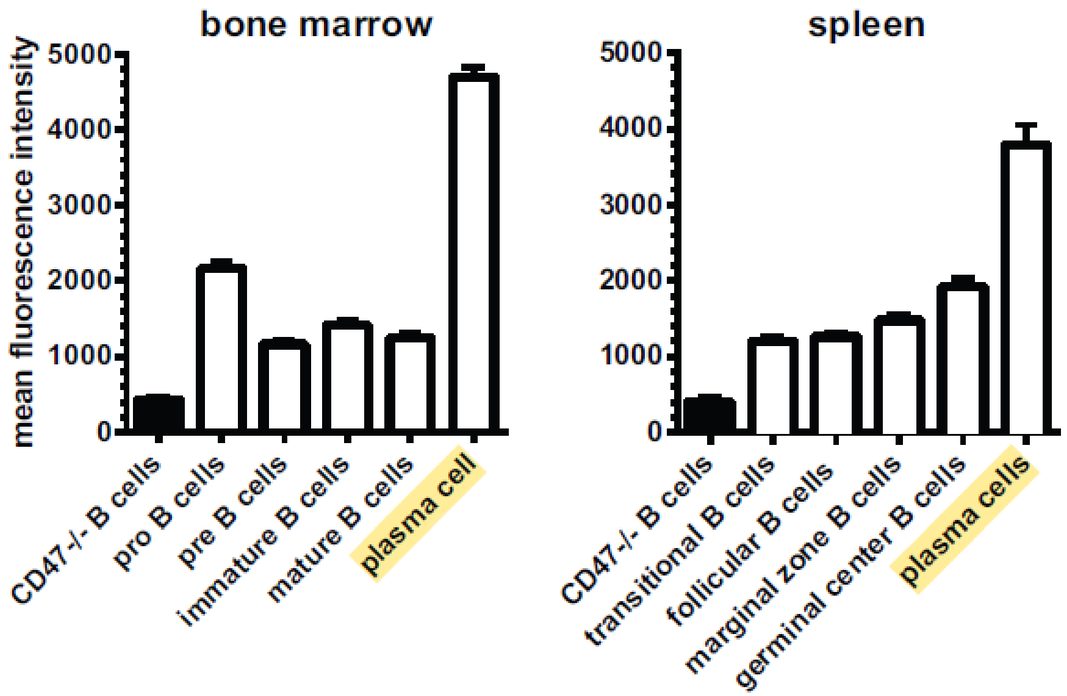
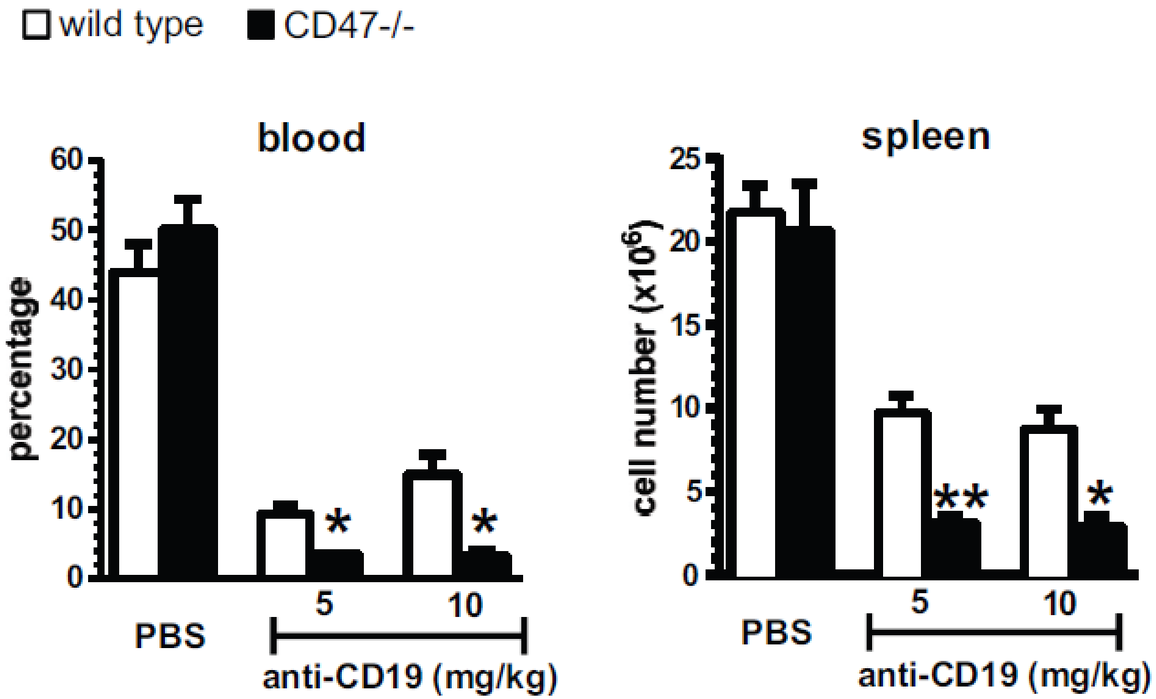
Expression of CD47 on B cell subsets



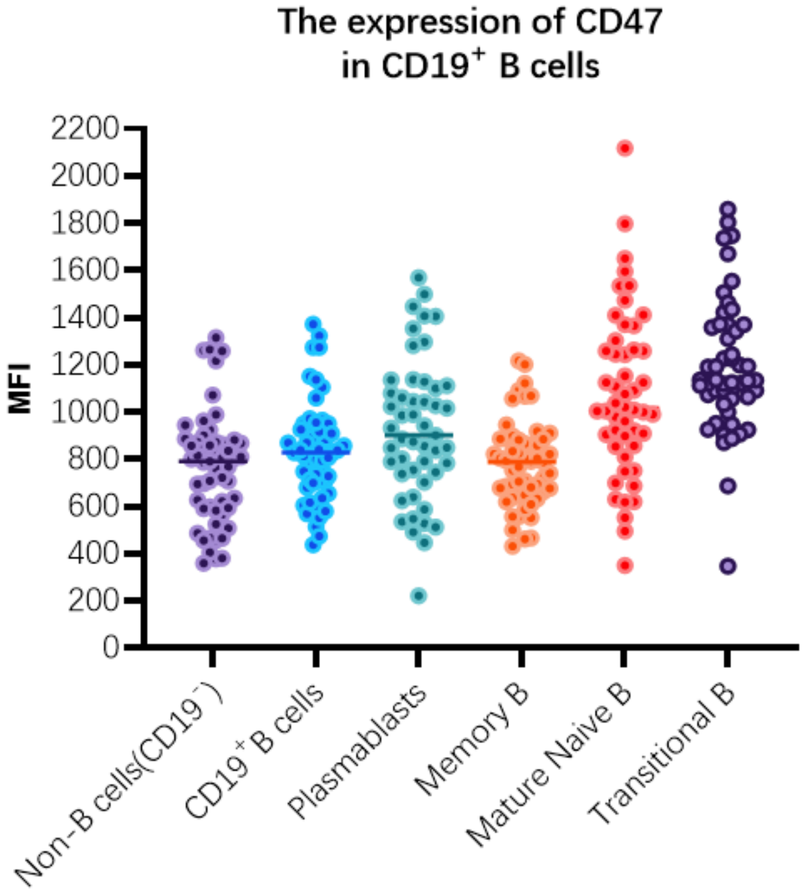
CD19^{+} B cell depletion is enhanced in CD47$^{-/-}$ mice

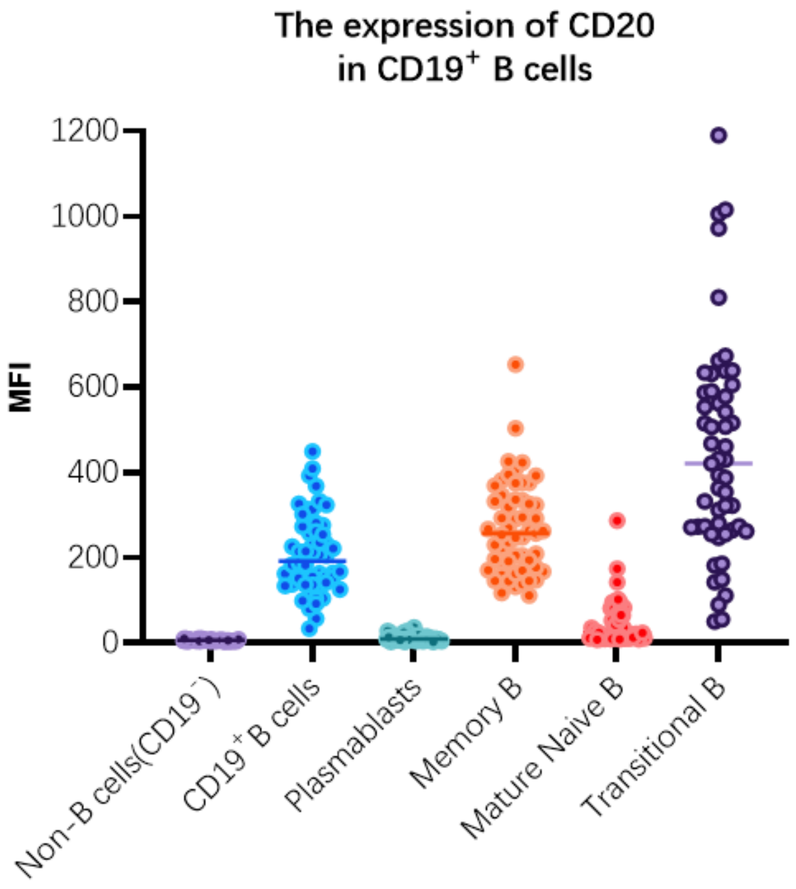


- Given its potent B-cell depletion ability, amulirafusp alfa (IMM0306) —a dual-targeting therapy against CD20 and CD47—shows strong potential as a promising treatment for autoimmune diseases.

Gallagher et al. Mol Immunol. 2017 May:85:57-65.

Dual Targeting of CD20 and CD47 Enhances Cell Lineage Coverage, Improving Therapeutic Potential





- In vitro analysis of SLE patient blood revealed:
  - CD47: High expression across B-cell subtypes (including plasmablasts), with no significant variation.
  - CD20: Minimal expression in plasmablasts and mature naïve B-cells vs other B-cell subsets.

Development Plan of Amulirafusp alfa (IMM0306) in Autoimmune Diseases

IND Approved in China

Systemic lupus erythematosus (SLE)
Phase Ib

Preliminary results presented here

Neuromyelitis optica spectrum disorder (NMOSD)
Phase Ib

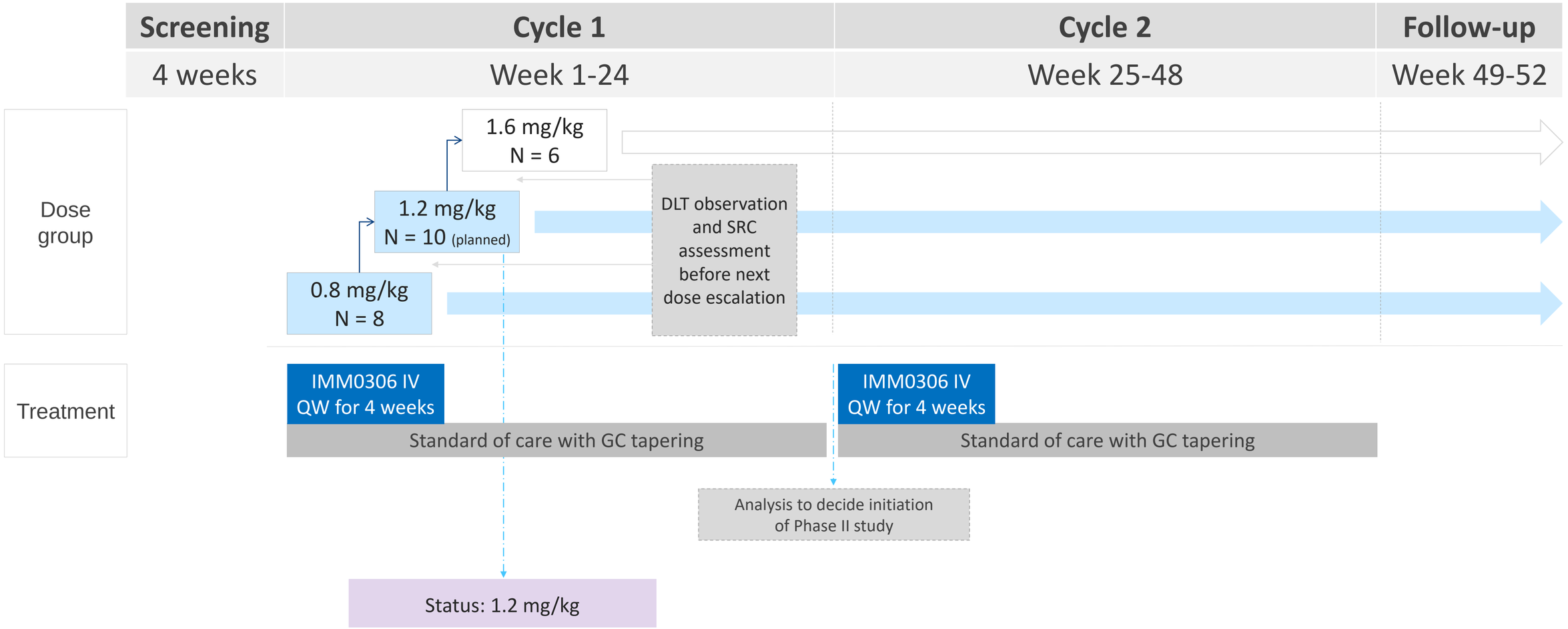
Lupus nephritis (LN)
Phase II

IND planned in US & China

Multiple sclerosis (MS)
China: Phase II
US: Phase Ib/II

Myasthenia gravis (MG)
China: Phase II
US: Phase Ib/II

Amulirafusp alfa (IMM0306) - Phase Ib Trial Design in SLE



GC: glucocorticoids. QW: Once a week. DLT: dose limiting toxicity. SRC: safety review committee.

Baseline Demographics and Disease Characteristics in SLE

	IMM0306 0.8mg/kg (N=8)	IMM0306 1.2mg/kg (N=8)	Total (N=16)
Female, n (%)	6 (75%)*	8 (100%)	14 (87.5%) *
Age (years), median (min, max)	35 (24, 63)*	38.5 (19, 49)	36 (19, 63) *
SLE disease duration (years), median (min, max)	9 (1, 24)*	3.5 (1, 13)	4.5 (1, 24) *
SLEDAI-2K, mean (SD)	10.25 (2.96)*	12.25 (4.83)	11.25 (4.00) *
BILAG-2004 organ domain involvement, n (%)			
2A or 1A	1 (12.5%)	2 (25%)	3 (18.8%)
2B	7 (87.5%)*	6 (75%)	13 (81.3%) *
PGA, mean (SD)	1.71 (0.45)*	1.58 (0.43)	1.65 (0.43) *
Serum Biomarkers, n (%)			
ANA positive	8 (100%)*	8 (100%)	16 (100%) *
Anti-dsDNA positive	4 (50%)	6 (75%)	10 (62.5%)
Low complement	5 (62.5%)*	5 (62.5%)	10 (62.5%) *
Proteinuria > 0.5 g/24h at baseline , n (%)	3 (37.5%)	3 (37.5%)	6 (37.5%)
Prior treatment, n (%)			
Glucocorticoids, n (%)	8 (100%)*	8 (100%)	16 (100%) *
Antimalarials, n (%)	7 (87.5%)*	8 (100%)	15 (93.8%) *
Immunosuppressive drug, n (%)			
Mycophenolate mofetil	6 (75%)	6 (75%)	12 (75%)
Azathioprine	3 (37.5%)	1 (12.5%)	4 (25%)
Cyclophosphamide	2 (25%)	1 (12.5%)	3 (18.8%)
Biologics, n (%)	2 (25%)	1 (12.5%)	3 (18.8%)
Organ-involvement, n (%)			
Skin, n (%)	6 (75%)*	6 (75%)	12 (75%)*
Joint, n (%)	4 (50%)*	5 (62.5%)	9 (56.3%)*
Renal, n (%)	4 (50%)	4 (50%)	8 (50%)
Hematology, n (%)	3 (37.5%)	2 (25%)	5(31.3%)

*Data cut-off June 6, 2025. *Including 1 patient who withdrew.*

IMM0306 is Well Tolerated in SLE Patients

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Adverse Events of 0.8 mg/kg cohort (up to week 31)

Period	Event	All TRAEs N=8	≥Grade 3 TRAEs N=8
During the DLT observation period	Patients experienced study related AEs	4 (50.0%)	1 (12.5%)
	Platelet count decreased	2 (25%)	1 (12.5%)
	Headache	1 (12.5%)	1 (12.5%)
	Anemia	1 (12.5%)	0
	Infusion reaction	1 (12.5%)	0
	Herpes simplex*	1 (12.5%)	0
	Fever	1 (12.5%)	0
	γ-GT Increased	1 (12.5%)	0
	Hyperuricemia	1 (12.5%)	0
	Acute gastroenteritis	1 (12.5%)	0
	Urinary infection#	1 (12.5%)	0
	Immune globulin↓	1 (12.5%)	0
After the DLT observation period	Acute bronchitis	1 (12.5%)	0
	Alkaline phosphatase increased	1 (12.5%)	0
	Sinus bradycardia	1 (12.5%)	0

Adverse Events of 1.2 mg/kg cohort (up to week 17)

Period	Event	All TRAEs N = 8	≥Grade 3 TRAEs N=8
During the DLT observation period	Patients experienced study related AEs	5 (62.5%)	1 (12.5%)
	Infusion reaction	2 (25%)	0
	Platelet count decreased	1 (12.5%)	1 (12.5%)
	Monocytes↓	1 (12.5%)	0
	ALT↑	1 (12.5%)	0
	AST↑	1 (12.5%)	0
	Creatine kinase↑	1 (12.5%)	0
	Hyperuricemia	1 (12.5%)	0
	Neutrophil ↑	1 (12.5%)	0
	Upper respiratory tract infection※	1 (12.5%)	0
	Urinary White Blood Cell ↑	1 (12.5%)	0
	Anemia	1 (12.5%)	0

- Two Grade ≥3 adverse events (platelet count decreased) occurred - one each in the 0.8 mg/kg and 1.2 mg/kg cohorts. Both cases resolved spontaneously within 4-5 days without intervention.

*Herpes simplex: Occurred after the first dose

#Urinary infection: Occurred after the first dose

※ Upper respiratory tract infection: Occurred after the 3rd dose

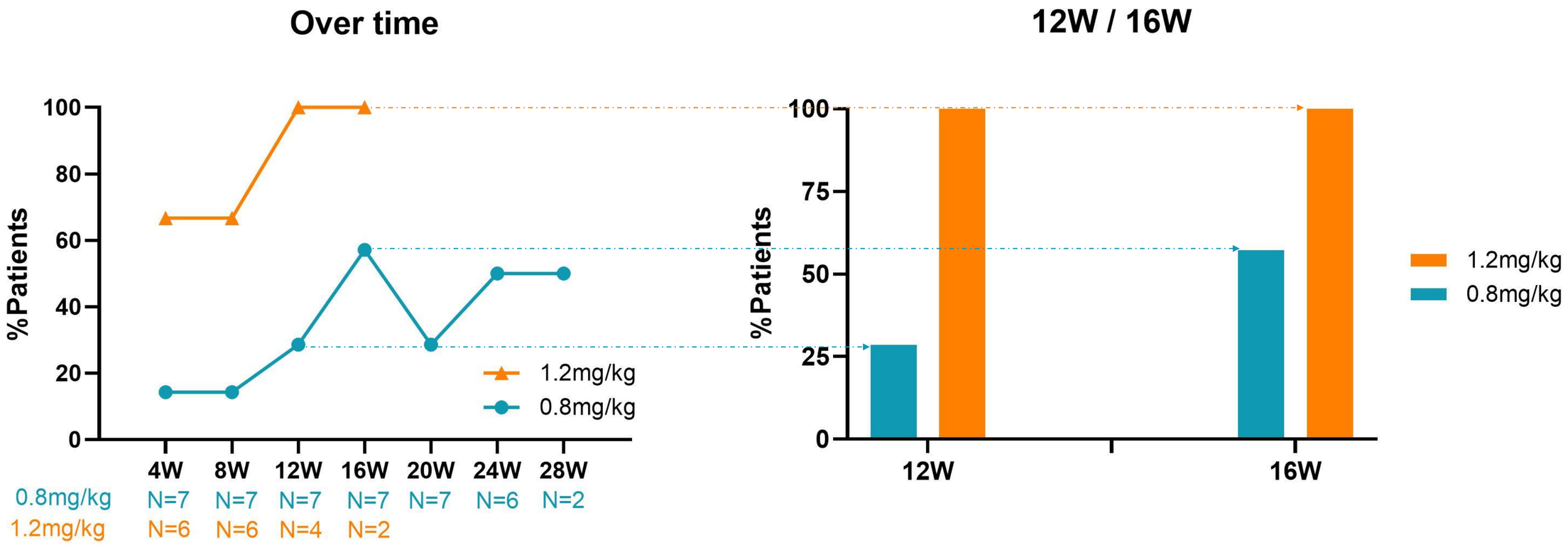
Data cut-off June 6, 2025.

8 subjects were enrolled in 0.8 mg/kg group with 7 subjects completed 4 doses (QW) and 1 withdrew voluntarily after one dose.

8 subjects were enrolled in 1.2 mg/kg group with 6 subjects completed 4 doses (QW), 1 completed 2 doses (QW) and 1 patient completed 1 dose.

Amulirafusp alfa (IMM0306) Shows Rapid, Dose-Dependent SLEDAI-2K Improvement

- Proportion of patients with ≥ 4 points reduction from baseline in SLEDAI-2K score



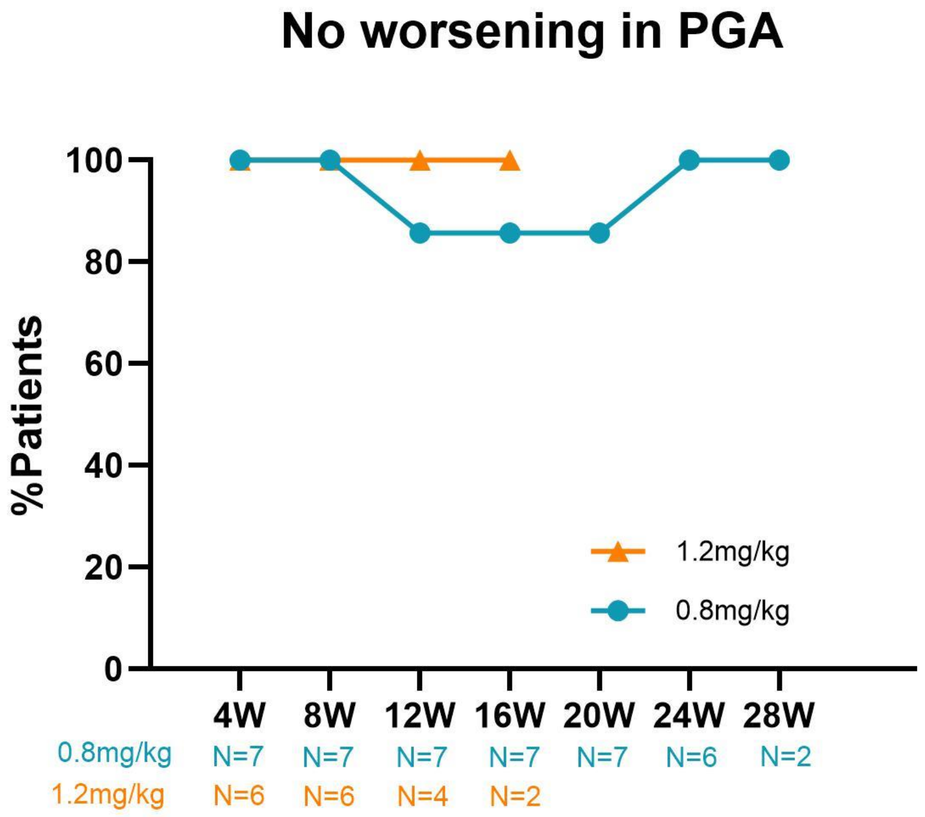
Data cut-off June 6, 2025.

Note: The patients included in the efficacy analysis had completed ≥4 doses and at least one efficacy evaluation (7 patients in 0.8mg/kg cohort, 6 patients in 1.2mg/kg cohort).

Strong Efficacy Signal in Preliminary Data of SLE Study

The baseline and symptom improvement of subjects

Dose cohort	Patient No.	BILAG-2004		
		Baseline	12W	24W
0.8mg/kg	patient 1	2A	2B	2B
	patient 2	2B	2B	2B
	patient 3	2B	2B	1B1C
	patient 4	2B	2C	2D
	patient 5	2B	2B	2B
	patient 6	2B	1B1D	1B1D
	patient 7	2B	2B	/
1.2mg/kg	patient 8	2B	1B1C	/
	patient 9	2B	1B1C	/
	patient 10	2B	2C	/
	patient 11	2B	1B1C	/
	patient 12	2B	/	/
	patient 13	2B	/	/
	patient 14	1A1B	/	/
	patient 15	1A	/	/



Data cut-off June 6, 2025.

Note: The patients included in the efficacy analysis had completed ≥4 doses and at least one efficacy evaluation (7 patients in 0.8mg/kg cohort, 6 patients in 1.2mg/kg cohort).

The light green indicates meaningful improvement in BILAG-2004. /: not time to evaluate yet.

Details of SLEDAI-2K, BILAG-2004 and PGA Measurement

Dose cohort	Patient No.	SLEDAI-2K								SLEDAI-2K reduction ≥4	BILAG-2004			PGA Maximum changes
		Baseline	4W	8W	12W	16W	20W	24W	28W		Baseline	12W	24W	
0.8 mg/kg	patient 1	8	8	8	8	8	8	8	8	-	2A	2B	2B	0.4↓
	patient 2	7	6	5	5	5	5	5	1	√	2B	2B	2B	0.2↓
	patient 3	10	10	10	10	6	8	9	/	-	2B	2B	1B1C	0.7↓
	patient 4	8	12	0	0	0	0	0	/	√	2B	2C	2D	1.3↓
	patient 5	16	16	16	17	16	14	10	/	√	2B	2B	2B	0.1↓
	patient 6	12	8	10	6	6	3	7	/	√	2B	1B1D	1B1D	1.1↓
	patient 7	9	8	14	11	5	8	/	/	-	2B	2B	/	0.3↓
1.2 mg/kg	patient 8	16	10	2	6	2	/	/	/	√	2B	1B1C	/	0.8↓
	patient 9	10	8	6	6	6	/	/	/	√	2B	1B1C	/	0.3↓
	patient 10	8	0	0	0	/	/	/	/	√	2B	2C	/	0.2↓
	patient 11	10	6	8	6	/	/	/	/	√	2B	1B1C	/	0.2↓
	patient 12	14	14	14	/	/	/	/	/	-	2B	/	/	0
	patient 13	8	4	4	/	/	/	/	/	√	2B	/	/	0.5↓
	patient 14	22	/	/	/	/	/	/	/	/	1A1B	/	/	/
	patient 15	10	/	/	/	/	/	/	/	/	1A	/	/	/

0.8mg/kg cohort

- **GC tapering:** 57.1% (4/7)
- **SLEDAI-2K reduced by ≥4:** 57.1 % (4/7)
- **PGA scores no worsening:** 100% (7/7)

1.2mg/kg cohort

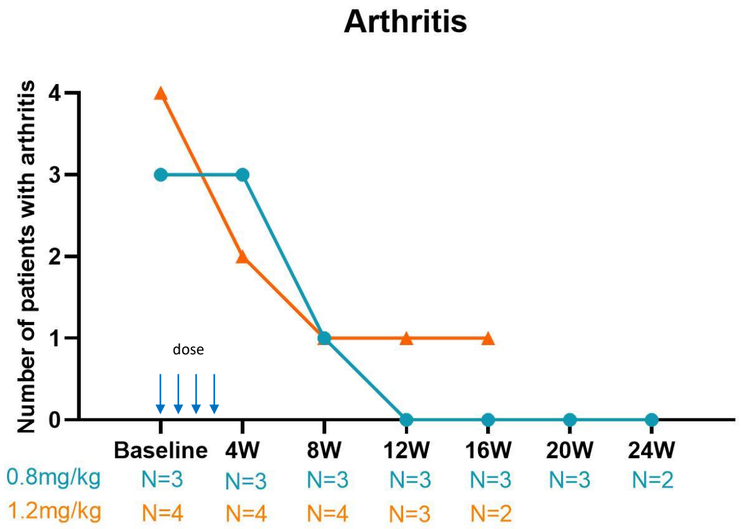
- **GC tapering:** 33.3% (2/6)
- **SLEDAI-2K reduced by ≥4:** 83.3% (5/6)
- **PGA scores no worsening:** 100% (6/6)

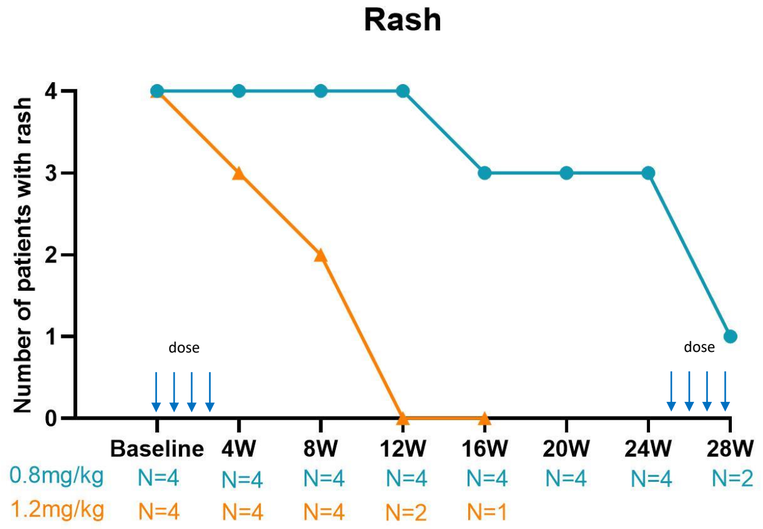
Data cut-off June 6, 2025.

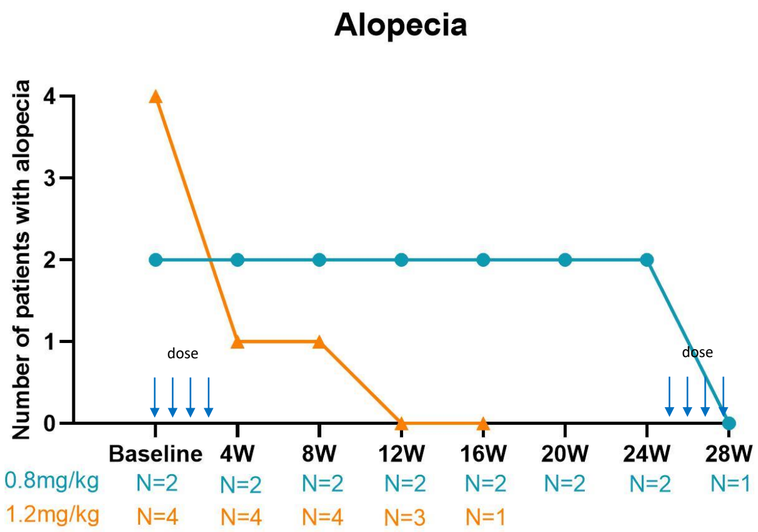
Note: The patients included in the efficacy analysis had completed ≥4 doses and at least one efficacy evaluation (7 patients in 0.8mg/kg cohort, 6 patients in 1.2mg/kg cohort).

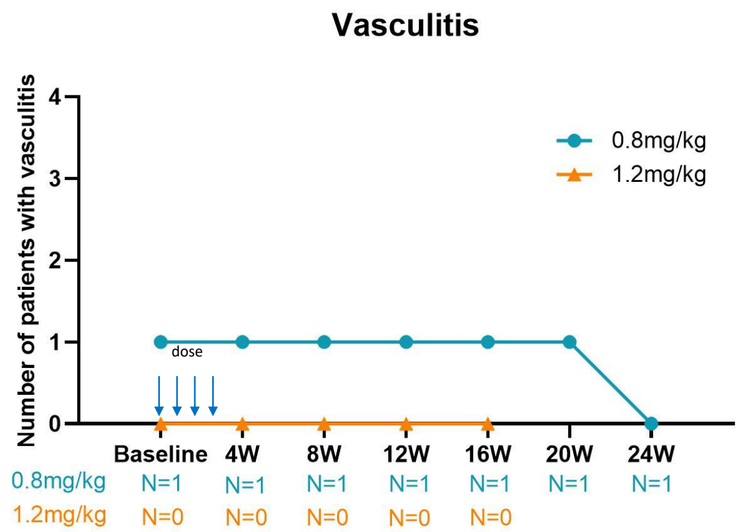
The light green indicates meaningful improvement in SLEDAI-2K, BILAG-2004 or PGA of a patient. /: not time to evaluate yet. √ : meet the corresponding criteria. -: no improvement.

Situation of Arthritis, Rash, Alopecia and Vasculitis are Improved



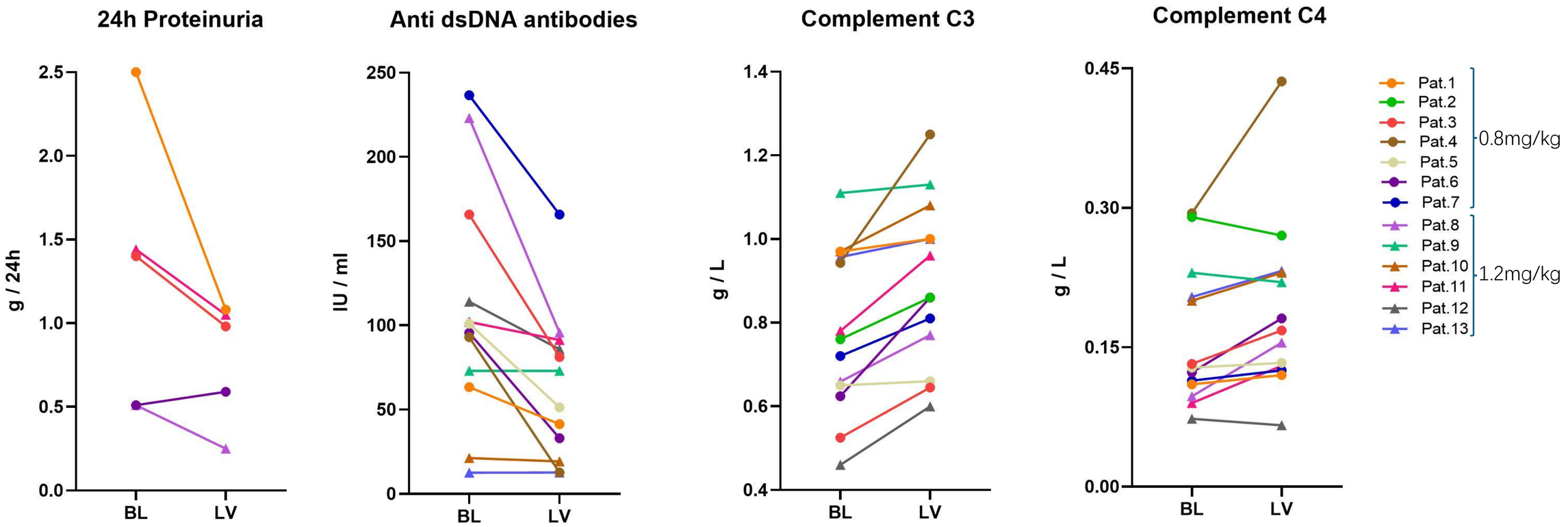






Data cut-off June 6, 2025.

Improvement is Generally Observed in 24h Proteinuria, Anti-dsDNA Antibodies and Complement C3/4



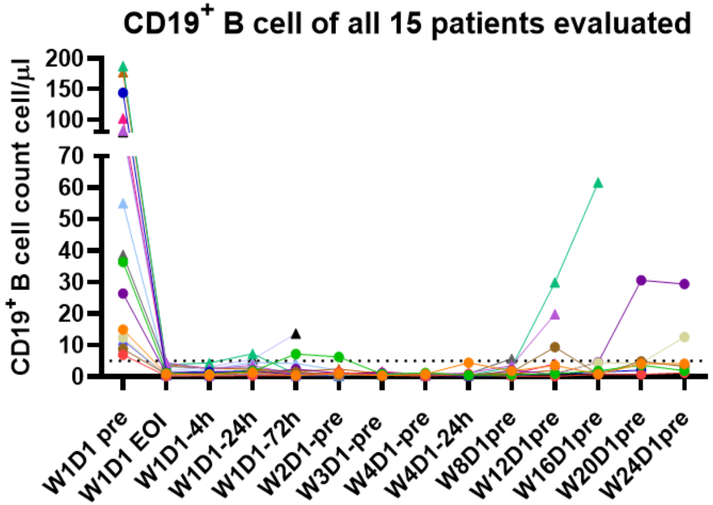
Data cut-off June 6, 2025.

BL: Baseline; LV: Latest Visit

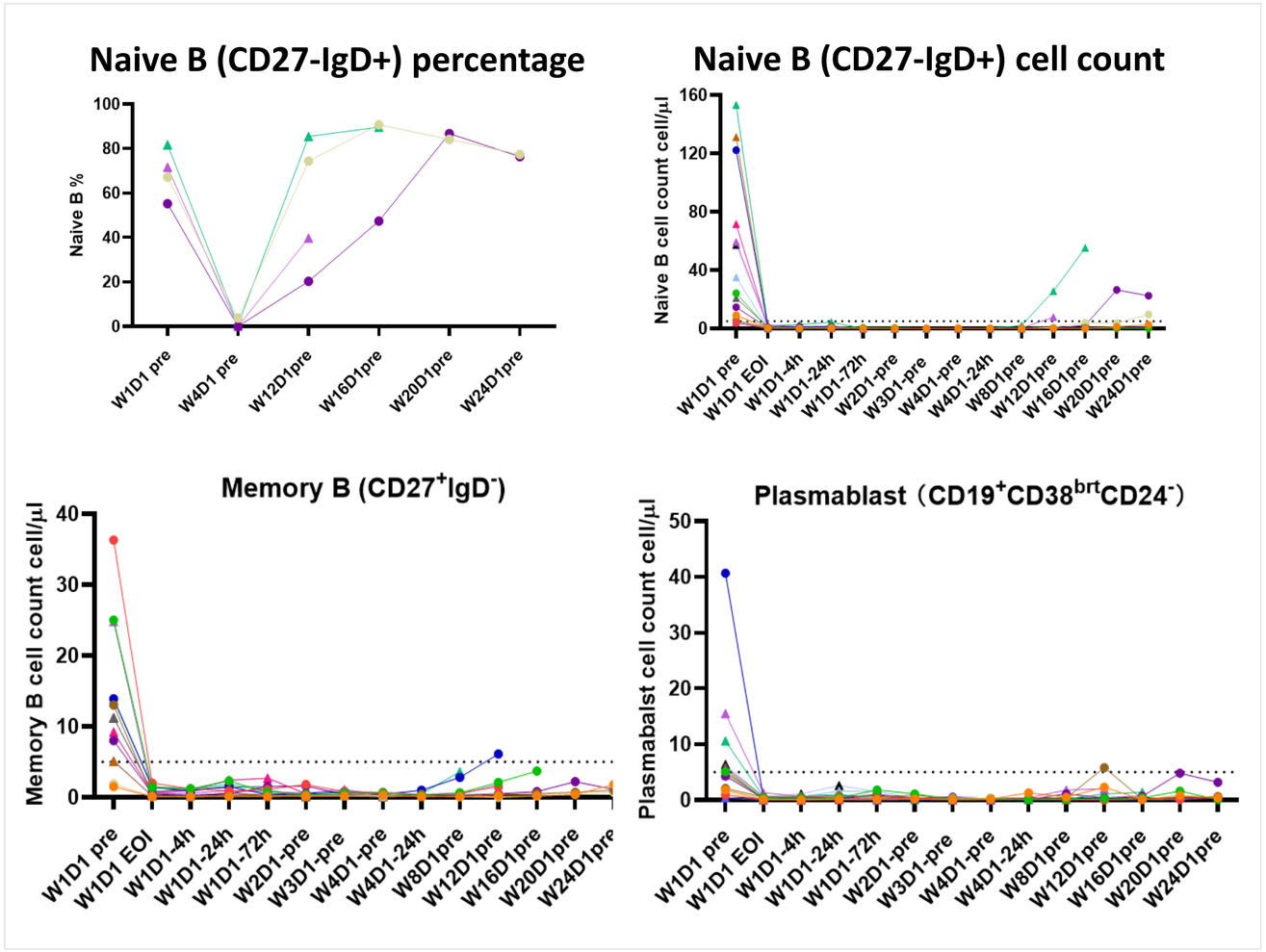
24h Protenuria: Of the patients with at least one post-medication examination data, 5 patients had 24-hour proteinuria >0.5 g/24 hours at baseline

Anti-dsDNA antibodies: Of the patients with at least one post-medication examination data, 1 patient was not included because of qualitative result

Efficient and Sustained B-cell Depletion with Immune Reconstitution Observed



4 patients showed a trend of immune reconstitution from W12



Amulirafusp alfa (IMM0306) Shows Best-in-disease Potential in SLE

	Amulirafusp alfa (IMM0306)	Mosunetuzumab[2]	Telitacicept[3]	Belimumab[4]
Target	CD47xCD20	CD3xCD20	BLyS, APRIL	BLyS
≥4 points reduction from baseline in patients with SLEDAI-2K ≥8	83.3% (5/6) Week8-16 [1]	66.7% (4/6) Week52	77.8% (49/63) Week48[3.1]	46.5% (127/273) Week52[4.1]
B-cell depletion right after infusion	Yes	n.a.	n.a.	n.a.
Cytokine release syndrome	0	33.3% (5/15)	n.a.	n.a.
Dose step-up	Not required	Required	Not required	Not required
Stage	Phase Ib	Phase Ib	Approved in China	Approved by FDA

n.a. not available

1. 1.2 mg/kg. 2. Chindalore et al. EULAR2025 POS1160. 3. Wu et al. Ann Rheum Dis 2023;0:1–13. BLyS: B lymphocyte stimulator; APRIL: a proliferation inducing ligand. 4. Furie et al. Arthritis Rheum. 2011 Dec;63(12):3918-30.

3.1 Approved dose (160 mg). 4.1 Approved dose (10mg/kg), base line SLEDAI score ≥ 6.

Thank you

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