SECTOR
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Healthcare Industry

Immunology 2026: Precision and control

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(§ The Korean version of this report was published on Apr 10)

Immunology 2026

Precision and control

The autoimmune disease market, once represented by drugs that broadly suppress inflammation in major diseases like rheumatoid arthritis and psoriasis (*eg*, the blockbuster drug Humira), previously grew around TNF inhibitors. Since then, with the emergence of IL-12/23, IL-17, IL-23, and JAK inhibitors, the market has evolved from simple immunosuppression to more precisely targeting the core immune axis for each disease. Recently, thanks to next-generation mechanisms such as FcRn, B-cell depletion, and bispecific antibodies, the autoimmune disease market has entered a stage where the key is which immune axis is targeted and how accurately.

The global market is already in full swing with next-generation blockbuster competition. AbbVie has reorganized its portfolio around Skyrizi and Rinvoq (after Humira), and Johnson & Johnson is targeting the follow-up market with Tremfya and next-generation IL-23 assets. Sanofi and Regeneron have grown a new disease frame called Type 2 inflammation through Dupixent. Major overseas companies are not competing with a single drug, but are expanding their long-term growth base by securing pipelines targeting multiple immune axes such as IL series, JAK, FcRn, and B cell targets through in-house development and M&As.

In Korea, investors should pay attention to HanAll Biopharma and AprilBio. HanAll Biopharma is growing its presence in the autoimmune disease area (centering on FcRn-class assets) with global partners, and AprilBio is showing the possibility of expanding its immune disease pipeline based on its long-acting platform. Although domestic autoimmune disease companies have not yet reached the commercialization stage at the level that global big pharmas have, HanAll Biopharma and AprilBio are considered noteworthy candidates in Korea as market demands are shifting towards more precise immune regulation and differentiated platforms. In addition, IMBiologics' OX40L/TNF-targeting AMB-101, which targets the upper axis, is also considered noteworthy in that it has already signed two out-licensing contracts (even before its proof of concept (PoC) has been confirmed).

A leader in FcRn therapeutics; HL161ANS

Batoclimab and HL161ANS

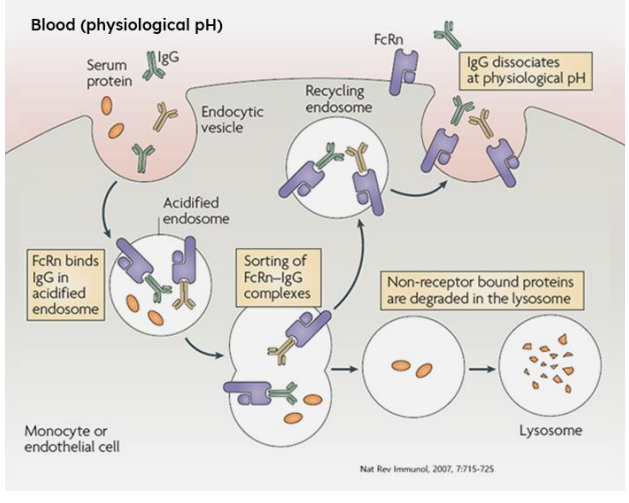
- **Owns a proprietary FcRn franchise:** HanAll Biopharma owns two proprietary assets: Batoclimab (HL161BKN, an anti-FcRn antibody) and HL161ANS (IMVT-1402, a next-generation anti-FcRn antibody). Both agents work by blocking FcRn to reduce pathogenic IgG autoantibodies, with expanding indications in antibody-mediated autoimmune diseases such as myasthenia gravis (MG), thyroid eye disease (TED), Graves' disease (GD), difficult-to-treat rheumatoid arthritis (D2T RA), Sjögren's syndrome, chronic inflammatory demyelinating polyneuropathy (CIDP), and cutaneous lupus erythematosus (CLE).
- While Batoclimab is the first-generation asset with established clinical data, HL161ANS is the next-generation candidate designed to minimize impact on albumin, enable convenient subcutaneous administration, and deliver faster and deeper IgG reduction.

Development stage by indication for Batoclimab vs HL161ANS

Project code	Indication	Preclinical	Phase 1	Proof-of-Concept	Pivotal	BLA/NDA Review
Batoclimab	중증근무력증 (MG)					(US/EU/Japan) (China)
	갑상선 안병증 (TED)					(US/EU/Japan) (China)
	그레이브스병 (GD)					(Germany)
	만성 염증성 다발성 신경병증 (CIDP)					(US/EU)
Imeroprubart (IMVT-1402)	그레이브스병 (GD)					(US/EU)
	류마티스 관절염 (ACPA+ D2T RA)					(US/EU)
	중증근무력증 (MG)					(US)
	만성 염증성 다발성 신경병증 (CIDP)					(US)
	쇼그렌 증후군 (SjD)					(US)
	피부 홍반성 루푸스 (CLE)				(US)	

Source: HanAll Biopharma, Samsung Securities

FcRn mechanism



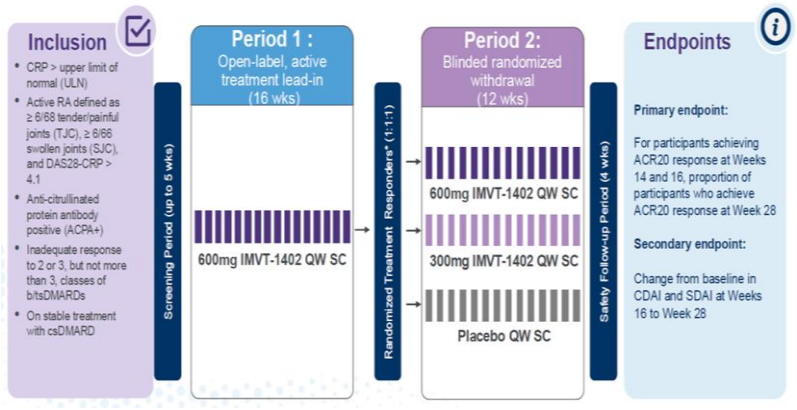
Source: HanAll Biopharma, Samsung Securities

HanAll Biophama and Immunovant's partnership

Partnership with Immunovant

- Immunovant recently reported Phase-III results for Batoclimab in TED. The trial did not meet its primary endpoint due mainly to a suboptimal dosing design that reduced the dose prior to the primary assessment window. In contrast, HL161ANS (IMVT-1402, a next-generation FcRn inhibitor) has demonstrated more potent IgG suppression. The dosing strategy issue observed with Batoclimab is not expected to recur with IMVT-1402 given its improved pharmacodynamic profile.
- Top-line Phase-II PoC results for IMVT-1402 in difficult-to-treat ACPA-negative rheumatoid arthritis (RA), and cutaneous lupus erythematosus (CLE) are anticipated in 2H26. Meanwhile, rival drug Nipocalimab's IRIS-RA trial failed to achieve statistical significance on its primary endpoint (DAS28-CRP). However, *post-hoc* analysis revealed that patients with high ACPA titers showed more than a two-fold greater response; statistically significant results were achieved using ACR20 as the endpoint.
- Leveraging this insight, the IMVT-1402 development program has been redesigned to reduce clinical risk and increase the probability of success: 1) the patient population has been restricted to ACPA-positive subjects; 2) the withdrawal design has been randomized (only those that respond after 14-16 weeks of open-label treatment are randomized to continue or discontinue); 3) the primary endpoint has changed to ACR20; and 4) a higher dose was selected to enhance the effect size.

IMVT-1402 RA clinical design



Source: Immunovant, Samsung Securities

IMVT-1402 vs Nipocalimab clinical design

Category	IMVT-1402 D2T RA	Nipocalimab IRIS-RA
Clinical status	Ongoing P2	Completed P2
Design	Randomized responders	Randomized all
Patient group	Refractory to 2 or more bD MARDs ACPA+/IgG	Refractory to 1 or more anti-TNF A CPA+ or RF+
Dosage	600mg SC QW	15mg/kg IV Q2W ~58% IgG reducti on
Primary endpoint	ACR20@28w	DAS28-CRP@12w Nipo 21.2% vs Placebo 10% (p=0.456)
Subgroup analysis		High ACPA patient group Nipo 40% vs Placebo 16.7%

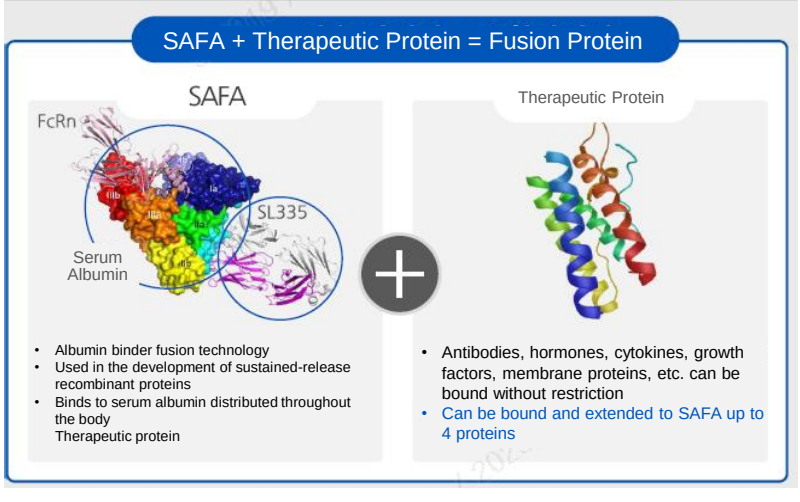
Source: Samsung Securities

Competitive advantage of the SAFA platform validated by clinical data

▶ Scalability of the SAFA platform

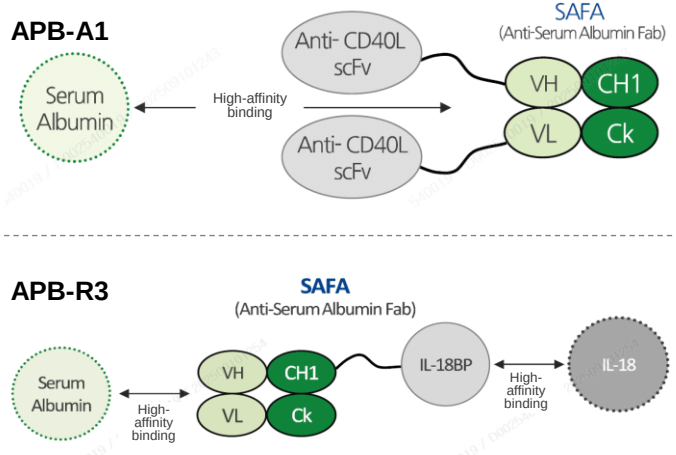
- AprilBio's SAFA platform leverages albumin binding to extend half-life, primarily enhancing dosing intervals and exposure duration for autoimmune disease therapeutics. Its lead asset, APB-A1 (Lu AG22515, CD40L), works by blocking the CD40L-CD40 signaling pathway, thereby reducing T-cell and B-cell activation and dampening inflammatory responses. It is developing a treatment for TED.
- APB-R3 (EVO301) is a fusion protein combining an IL-18 binding protein with SAFA. While its indication aligns more closely with autoinflammatory diseases, its development further demonstrates the versatility and technological value of the SAFA platform. As such, APB-R3 should be evaluated alongside APB-A1 to fully assess the platform's broad applicability.

SAFA platform



Source: AprilBio, Samsung Securities

APB-A1, APB-R3 structure



Source: AprilBio, Samsung Securities

PoC confirmed; now the real game begins

▶ Validation of the SAFA platform's technology

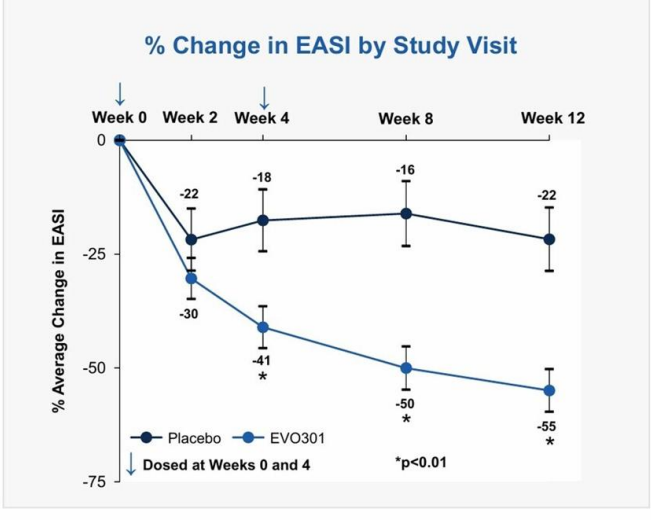
- Partner Lundbeck is expected to present the final Phase-Ib results for APB-A1 (Lu AG22515) in TED at the Endocrine Society 2026. Following this, the company is expected to accelerate its Phase-II trial design—separating acute and chronic patient cohorts—and expand the indication to other neuroimmunological diseases such as multiple sclerosis (MS).
- Partner Evommune in Feb 2026 achieved its primary endpoint in the Phase-IIa top-line results for APB-R3 (EVO301) in atopic dermatitis. A Phase-IIb subcutaneous formulation study is planned to define the optimal dose. Additionally, the company intends to initiate a Phase-II trial for ulcerative colitis as the next indication, with further expansion into IL-18-mediated diseases being actively considered.

APB-A1 competing drug status

	AT-1501 Tegoprubart	SAR-441344 Frexalimab	CDP7657 Dapirolizumab	HZN-4920 Dazodalibep	APB-A1
Manufacturer	Eledon	Sanofi	UCB/Biogen	Amgen/Horizon	AprilBio
Indication	ALS	Multiple sclerosis	Lupus	Sjogren's syndrome	Thyroid eye disease
Development stage	Preparing for P3	Ongoing P3	P3 Success	Ongoing P3	Entered P1b in Jan 2025
Structure	IgG with mutant Fc	IgG with unglycosylated Fc	Fab-PEG	Tn-3-HAS fusion	SAFA-fusion
Possibility of Immuno-genicity	Low	Low	Low	High	Low
Possibility of Throm-boembolism	0 (probably)	0 (probably)	X	X	X
Commercial viability	High	High	Medium	High	High

Source: AprilBio, Each company, Samsung Securities

APB-R3 P2a top-line results



% Average change in EASI is LS Mean

Source: Evommune, Samsung Securities

Autoimmune pipeline centered on upper-tier targets

▶ Simultaneous targeting of OX40L and TNF

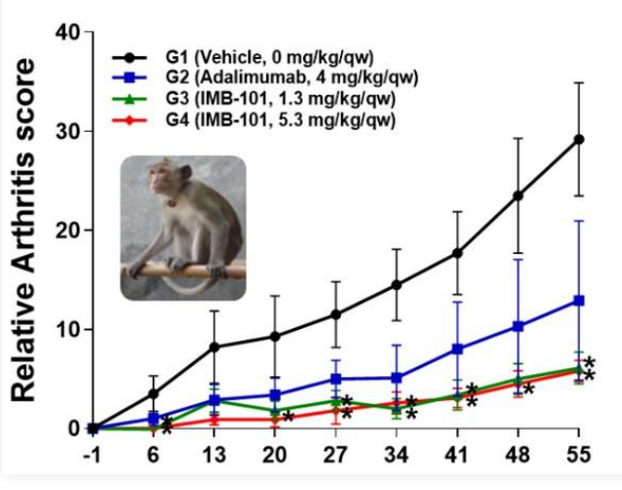
- **IMB-101:** IMB-101 is a dual antibody simultaneously targeting OX40L and TNF, currently advancing into Phase-II trials for hidradenitis suppurativa (HS) in partnership with Navigator Medicines. OX40L is a co-stimulatory pathway in inflammatory tissue, which is a higher immune regulatory pathway that minimizes innate inflammation through TNF inhibition (as validated by Humira and others). Preclinical studies demonstrated a reduction in inflammatory markers at just one-quarter the dose of Humira, alongside measurable improvements in joint and bone damage-related biomarkers.
- First-in-human dosing began in Mar 2026, with PoC results anticipated in 2H27. Prior to PoC validation, global rights (excluding Asia, including Japan) were licensed to Navigator Medicines in Jun 2024, and Asian rights (excluding Korea and Japan) to Huadong Medicine in Aug 2024, sustaining strong market anticipation for the PoC's success.
- **IMB-102:** IMB-102, a monospecific anti-OX40L antibody, is under further development primarily for atopic dermatitis, with pipeline valuation expected to be reassessed upon the successful PoC demonstration of IMB-101.

OX40-related global competing pipeline status

Drug name	Company	Target	Indication
Brivekimig	Sanofi	OX40L+TNFα	HS (P2b), T1D (stage 3, P2a), CD (P2b), UC (P2b)
NAV-240	Navigator Medicines/IM Biologics	OX40L+TNFα	HS (P2a)
NAV-242	Navigator Medicines/IM Biologics	OX40L+TNFα	Inflammatory autoimmune diseases focusing on HS (P1)
Amlitelimab	Sanofi	OX40L	AD (preparing for approval), asthma (P2)
IMB-102	IM Biologics	OX40L	AD (preparing to enter P1)
Oxelumab / RG4930	Roche/Genmab	OX40L	Asthma, allergic rhinitis (development suspended in 2011)
IMG-007	Inmagene	OX40	AD (P2b), alopecia areata (P2a)
STAR-0310	Astria Therapeutics	OX40	AD (P1a)
Telazorlimab	In-licensed asset of Astria, original developer IGI/Ichnos	OX40	AD (P2b), alopecia areata (P2a)
Rocatinlimab	Kyowa Kirin/Amgen	OX40	AD, asthma, PN (prurigo nodularis) (development suspended in Mar 2026)
APG279	Apogee Therapeutics	IL-13+OX40L	AD (P1b)

Source: Each company, Samsung Securities

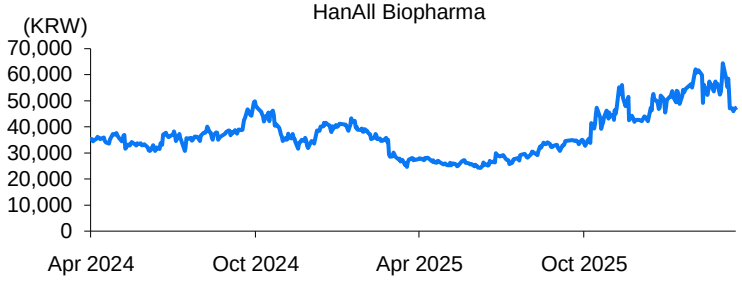
IMB-101 primate model efficacy evaluation



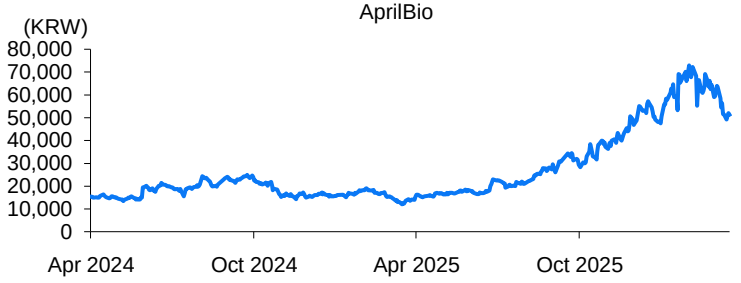
Source: IMBiologics, Samsung Securities

Target price/Rating changes in past two years (as of Apr 10)

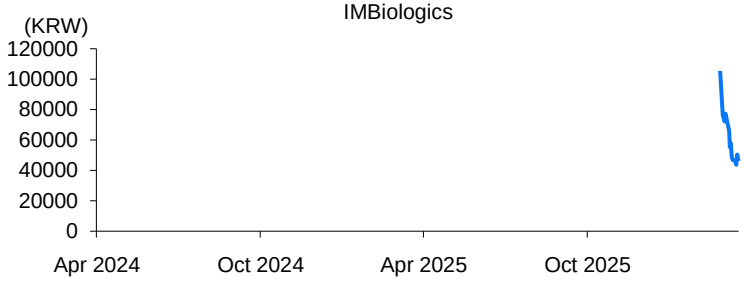
HanAll Biopharma



AprilBio



IMBiologics



Target price/Rating changes in past two years

HanAll Biopharma	
Date	2026/4/30
Recommendation	Not Rated
Target price (KRW)	n/a
Gap* (average)	
(max or min)**	

AprilBio	
Date	2026/4/30
Recommendation	Not Rated
Target price (KRW)	n/a
Gap* (average)	
(max or min)**	

IMBiologics	
Date	2026/4/30
Recommendation	Not Rated
Target price (KRW)	n/a
Gap* (average)	
(max or min)**	

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BUY	Expected to increase in value by 15% or more within 12 months and is highly attractive within sector
HOLD	Expected to increase/decrease in value by less than 15% within 12 months
SELL	Expected to decrease in value by 15% or more within 12 months

Industry

OVERWEIGHT	Expected to outperform market by 5% or more within 12 months
NEUTRAL	Expected to outperform/underperform market by less than 5% within 12 months
UNDERWEIGHT	Expected to underperform market by 5% or more within 12 months

* Note: Effective Jul 27, 2023, BUY, HOLD, and SELL criteria are based on expectations of share-price moves of 15% or more within 12 months

Percentage of ratings in 12 months prior to 2026.03.31

BUY(85.2%)·HOLD(14.8%)·SELL(0%)

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