유한양행 기업설명회

2025. 2Q

유한양행

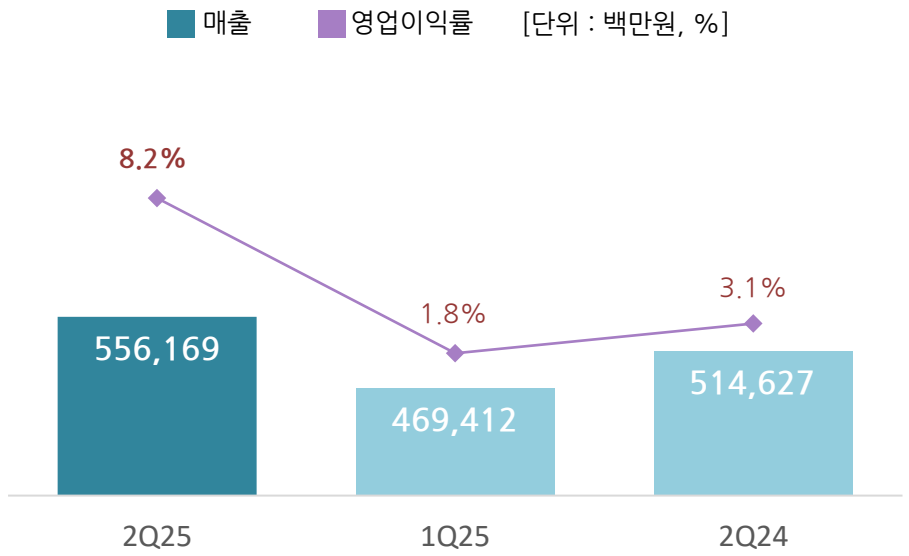
2025년 2분기 실적 분석

유한양행

별도

[단위 : 백만원]

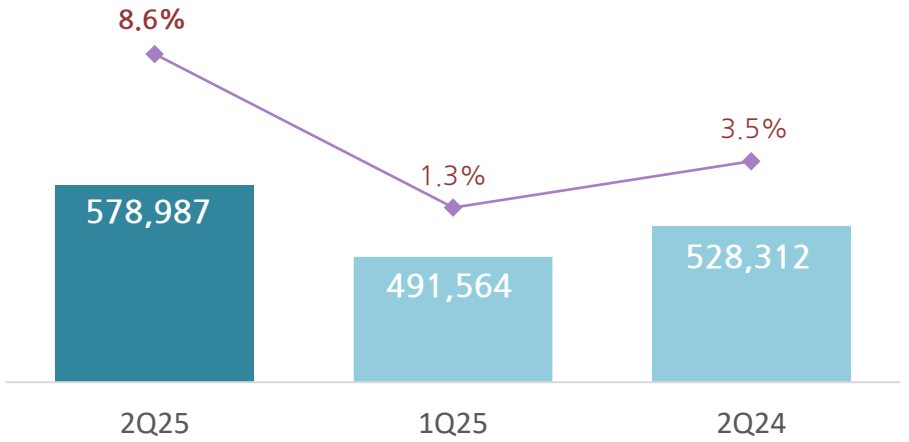
과 목	2Q25	1Q25	QoQ	2Q24	YoY
매출액	556,169	469,412	18.5%	514,627	8.1%
라이선스 수익	25,543	3,976	542.4%	555	4502.3%
매출원가	375,014	336,415	11.5%	365,113	2.7%
매출원가율	67.4%	71.7%	-4.3%p	70.9%	-3.5%p
R&D 비용	54,446	50,199	8.5%	53,457	1.9%
광고선전비	18,846	12,478	51.0%	25,829	-27.0%
영업이익	45,628	8,645	427.8%	15,731	190.0%
당기순이익	39,000	39,331	-0.8%	24,525	59.0%



연결

[단위 : 백만원]

과 목	2Q25	1Q25	QoQ	2Q24	YoY
매출액	578,987	491,564	17.8%	528,312	9.6%
영업이익	49,861	6,420	676.7%	18,542	168.9%
당기순이익	44,001	10,009	339.6%	31,912	37.9%



2025년 2분기 사업부 및 주요 품목 실적

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분기별 사업부 실적 (별도기준)

[단위 : 백만원]

구분		2Q25	1Q25	QoQ	2Q24	YoY
약품 사업	비처방	57,430	54,313	5.7%	52,365	9.7%
	처방	287,652	275,468	4.4%	286,721	0.3%
	소계	345,082	329,781	4.6%	339,086	1.8%
생활건강사업		68,831	46,741	47.3%	75,220	-8.5%
해외사업		114,785	87,363	31.4%	97,180	18.1%
라이선스 수익		25,543	3,976	542.4%	555	4502.3%
기타(임대, 수탁 등)		1,928	1,551	24.3%	2,585	-25.4%
매출액		556,169	469,412	18.5%	514,626	8.1%

주요 품목 실적

[단위 : 백만원]

구분	품목	1H25	YoY	1H24
비처방	안티푸라민(소염진통)	17,319	-4.9%	18,210
	엘레나(유산균)	11,616	-18.3%	14,225
	마그비(영양제)	9,729	-1.3%	9,861
	비판텐(상처치료제)	9,180		
	비타민씨(영양제)	7,856	27.9%	6,143
처방	자디앙(당뇨병)	52,380	2.1%	51,305
	트윈스타(고혈압)	44,814	-7.2%	48,295
	로수바미브(이상지질혈증)	38,236	4.4%	36,623
	트라젠타(당뇨병)	36,818	-15.2%	43,394
	비리어드(B형간염)	35,979	-3.7%	37,346
	빅타비(HIV)	34,034	0.8%	33,762
	베믈리디(B형간염)	32,390	8.6%	29,813
	글리벡(백혈병)	26,203	3.9%	25,214
	코푸시럽/정(호흡기)	18,737	-19.2%	23,189
	페마라(항암제)	13,745	33.6%	10,291

주요 혁신신약 파이프라인

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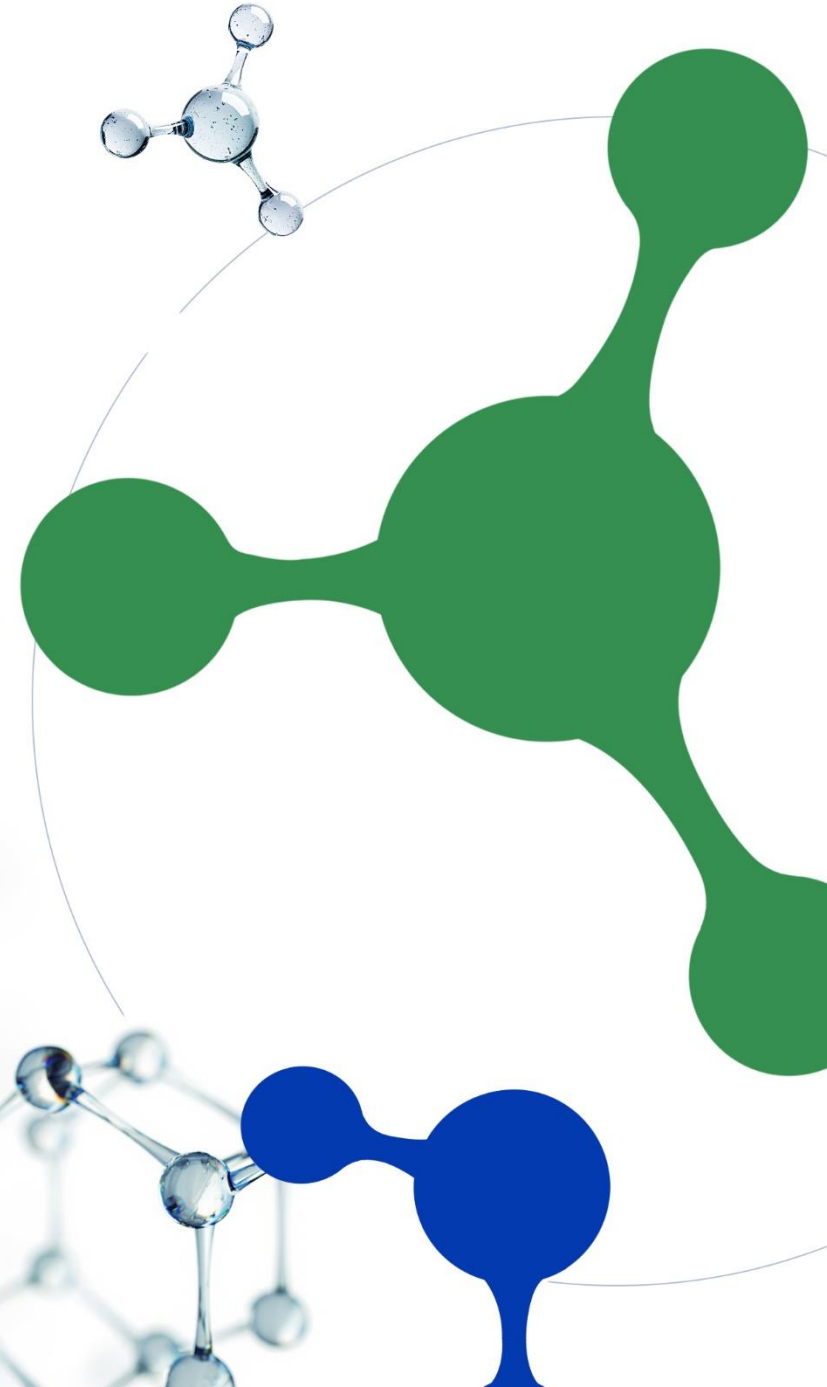
* Black 합성신약, Blue 바이오신약

약물	타겟	적응증	후보물질	비임상	임상 1상	임상 2상	임상 3상	Licensor	Licensee
LAZERTINIB	EGFR 돌연변이 3세대 TKI	EGFR돌연변이 비소세포폐암	단독요법 (유한) 글로벌 3상 Amivantamab 병용요법 (J&J) 글로벌 3상					GENOSCO	Johnson&Johnson Innovative Medicine
YH14618 (Remedisc)	TGF-β	퇴행성 디스크						EnsolBio sciences	SpineBiopharma
YH12852 (PCS12852)	5-HT receptor	위마비증							Processa Pharmaceuticals
YH35324	IgE	Allergy (CSU, 천식, AD)						GI innovation	
YH32367	Her2/4-1BB	유방암, 위암, 담관암 등						ablbio	
YH42946	Her2, EGFR	Her2돌연변이 폐암, 위암 등						JINTS BIO	
YH35995	GCS	고셔병, 파브리병						GC	
YH32364	EGFR/4-1BB	두경부암, 위암, 대장암 등						ablbio	
YH45057	Androgen receptor	전립선암						Ubix Therapeutics	
YH44529	SOS1	고형암						Cyrus KANAPH	

Progress & Integrity

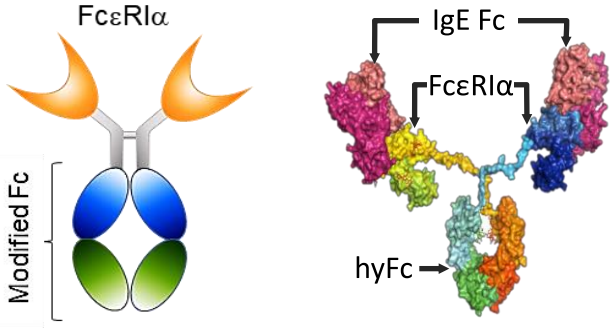
Lesigercept (YH35324)

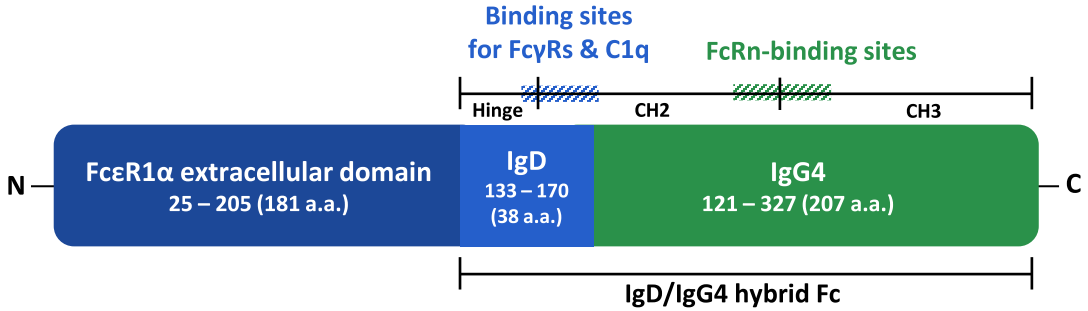


YH35324 (IgE_{Trap}-modified Fc) Structure

- YH35324 has fused FcεR1α's extracellular domain to a modified Fc to enable affinity to IgE and anti-FcεR1α antibodies, while achieving long-acting and better safety properties.
- By utilizing FcεR1α's extracellular domain, YH35324 works as an IgE trap and also binds to anti-FcεR1α antibodies.

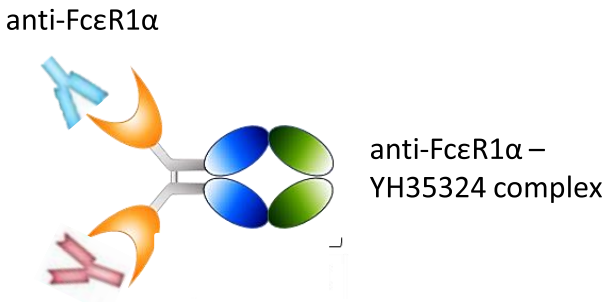
Structure of YH35324





→ **Long-acting 'hyFc' Fusion Platform:**
Clinically validated in multiple Ph 3 studies

Binding formations of YH35324



Modified Fc
IgD Hinge
▪ Highly flexible & natural (Maintains biological activity)
IgG4 Fc
▪ Longer acting (FcRn-mediated recycling) ▪ Better safety (No induction of ADCC or CDC)

YH35324 Target Product Profile

Category		Description/Expectation
Mode of Action		Long-acting IgE_{TRAP}-Fc fusion protein (human FcεRIα extracellular domain fused to human IgD/IgG4 modified Fc) • Binds circulating free IgE antibodies, preventing their binding to FcεRIα and CD23 on mast cells/basophils and the degranulation response • Binds functional IgG autoantibodies targeting the high-affinity IgE receptor (FcεRI)
Indications / Target Patients		• **Chronic spontaneous urticaria (CSU)**: Anti-IgE therapy naïve and omalizumab non-responders, patients with autoimmunity/high IgE levels • IgE-mediated diseases: Atopic dermatitis, allergic asthma, food allergy, chronic inducible urticaria, nasal polyps, etc.
Unmet Medical Needs	**CSU**	• Only 30% of patients treated with omalizumab experience a complete response. Approximately 45% of CSU patients harbor autoantibodies and these patients have delayed responses to anti-IgE therapies.[1] • Omalizumab has a black box warning for anaphylaxis.[2]
	Additional IgE-mediated allergic diseases	• Allergic asthma: 5-10% of severe asthma patients do not experience adequate symptom control with current therapies. • Atopic Dermatitis: Severe and recalcitrant atopic dermatitis, associated with very high IgE levels. • Food allergy: Oral immunotherapy carries procedure-related risks and requires frequent visits over long-term treatment. Despite the difficulties and high cost, the success rate for desensitization is modest.[1] • Chronic Inducible Urticaria (CIndU): In many patients, CIndU is not controlled by conventional H1-antihistamines.[3]
Clinical Benefits		• Faster onset, greater potency of IgE suppression and longer duration of effect • Higher complete response rate than omalizumab regardless of autoantibody status
Clinical Risks		• Very low to negligible risk of immunogenicity. Eliminated Fc binding region implicated in IgG-mediated anaphylaxis. • Fewer injection site reactions
Dosing Regimen		• Subcutaneous injection, once every 4 weeks
IP Status		• Composition of matter patent protected for 2039+ (without patent term extension) • PCT application entered into 21 countries including US, EU, CN, JP and granted in 9 countries
Competitive Landscape		• Anti-IgE therapies: Omalizumab (Xolair®, Novartis), Ligelizumab (Ph 3, Food allergy, Novartis) • Anti-BTK therapy (Ph 3, CSU, Novartis), anti-C-kit therapy (Ph 2, CSU, Celldex) • Anti-cytokine, anti-JAK therapies (AD)

[1] Consultation meeting with key opinion leaders at AAAAI2019; [2]Xolair® Prescribing Information. FDA; [3]J Allergy Clin Immunol. 2018; 141(2): 638-649.

YH35324 Exhibits More Potent and Durable Binding to IgE vs Omalizumab

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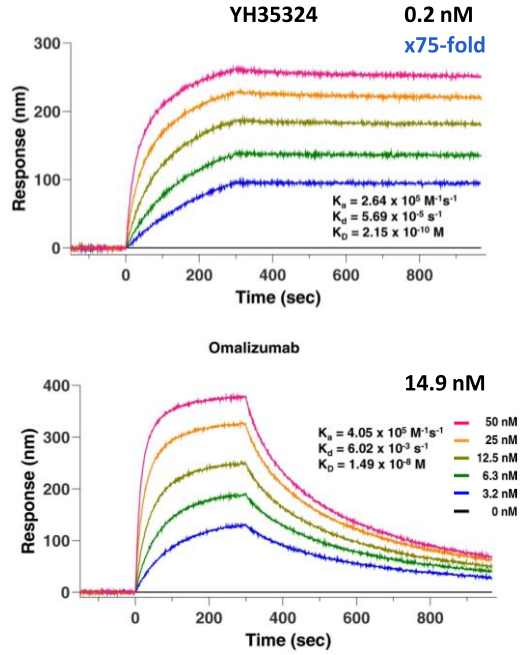
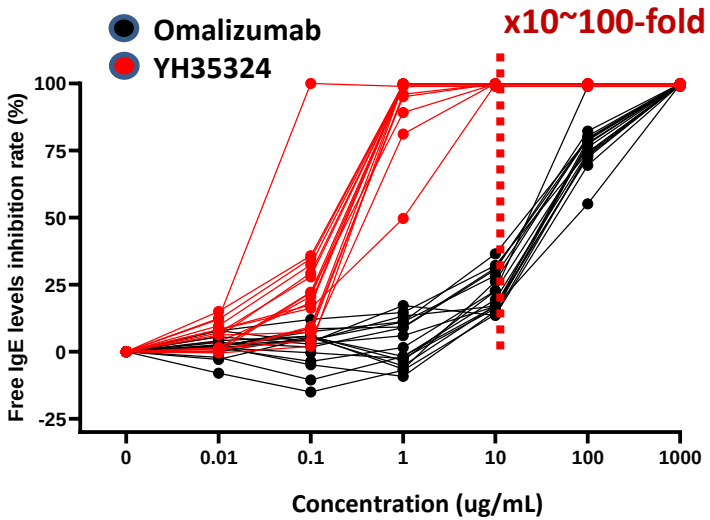
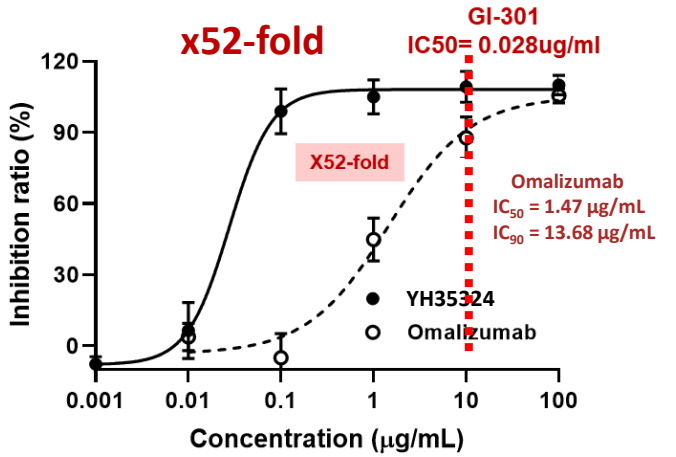
Stronger and more durable binding to IgE



Stronger suppression of free IgE in CSU patient serum



Stronger suppression of mast cell degranulation



Produced by Prof. HS Park

Baseline free IgE levels in CSU Patients (N=17) ranges 147.6-3,221.6 ng/mL IgE (61.5-1,342.3 IU/mL)
* Free IgE level in serum of CSU patients measured by ELISA

YH35324 demonstrated greater IgE suppression and more potent inhibition of mast cell degranulation compared to the approved drug, omalizumab.

*Analyzed by surface plasmon resonance (SPR) system
** Analyzed by the label-free biolayer interferometry (BLI) Octet® system

YH35324 promises more rapid, complete and durable disease control

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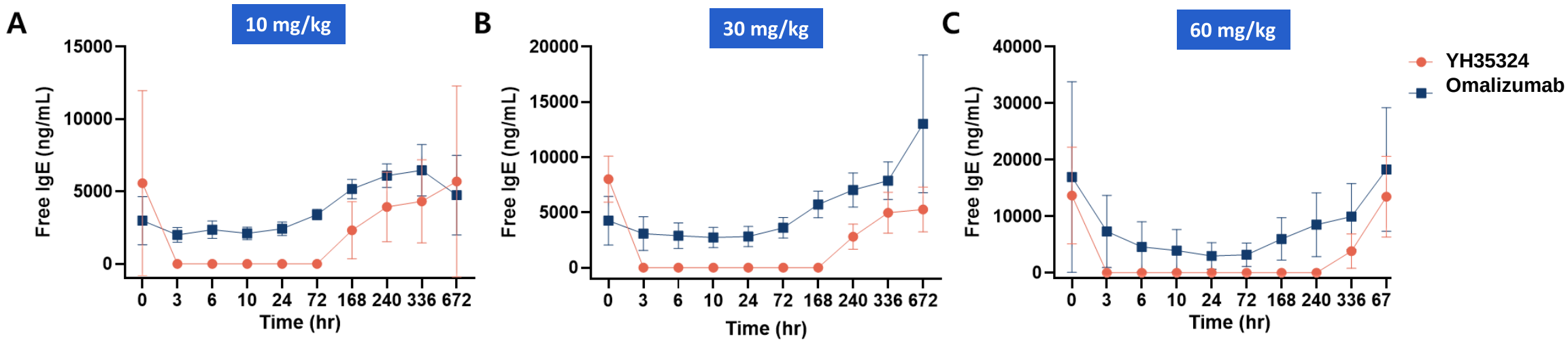
Mean free IgE levels following single SC injection in monkeys with high baseline IgE levels



Baseline Free IgE	10 mg/kg	30 mg/kg	60 mg/kg
YH35324	4342 ± 4689 ng/mL (1809 ± 1953 IU/mL)	5966 ± 1560 ng/mL (2486 ± 650 IU/mL)	8772 ± 6689 ng/mL (3655 ± 2787 IU/mL)
Omalizumab	2401 ± 1270 ng/mL (1001 ± 529 IU/mL)	3293 ± 1966 ng/mL (1327 ± 819 IU/mL)	6740 ± 2977 ng/mL (2808 ± 1240 IU/mL)

Cynomolgus monkey, N=4/group, female
Age: 3-4 years old
Body weight: 2.52-3.07 kg
Baseline free IgE levels: 1234.6 - 14778.8 ng/mL

Cynomolgus monkey, N=4/group, female
Age: 3-4 years old
Body weight: 2.26-2.81 kg
Baseline free IgE levels: 2617.6 - 9876.4 ng/mL

N=3/group
Baseline free IgE levels: 4148.9 - 36092.7 ng/mL

YH35324 reduced free IgE levels more rapidly than omalizumab in monkeys with high baseline IgE levels.

YH35324-101: Study Design

Study Title: A First-in-Human, Randomized, Double-Blind, Placebo/Active Controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Following Subcutaneous Injections of YH35324 in Atopic Healthy Subjects or Subjects with Mild Allergic Diseases

Target population

- Healthy subjects or subjects with mild allergic disease aged 19 - 55 years with atopy which is defined as having ≥ 1 positive result for inhalant or food allergens in a skin prick test and/or ImmunoCAP® specific IgE test, and serum total IgE levels of ≥ 30 IU/mL

Primary objective and endpoint

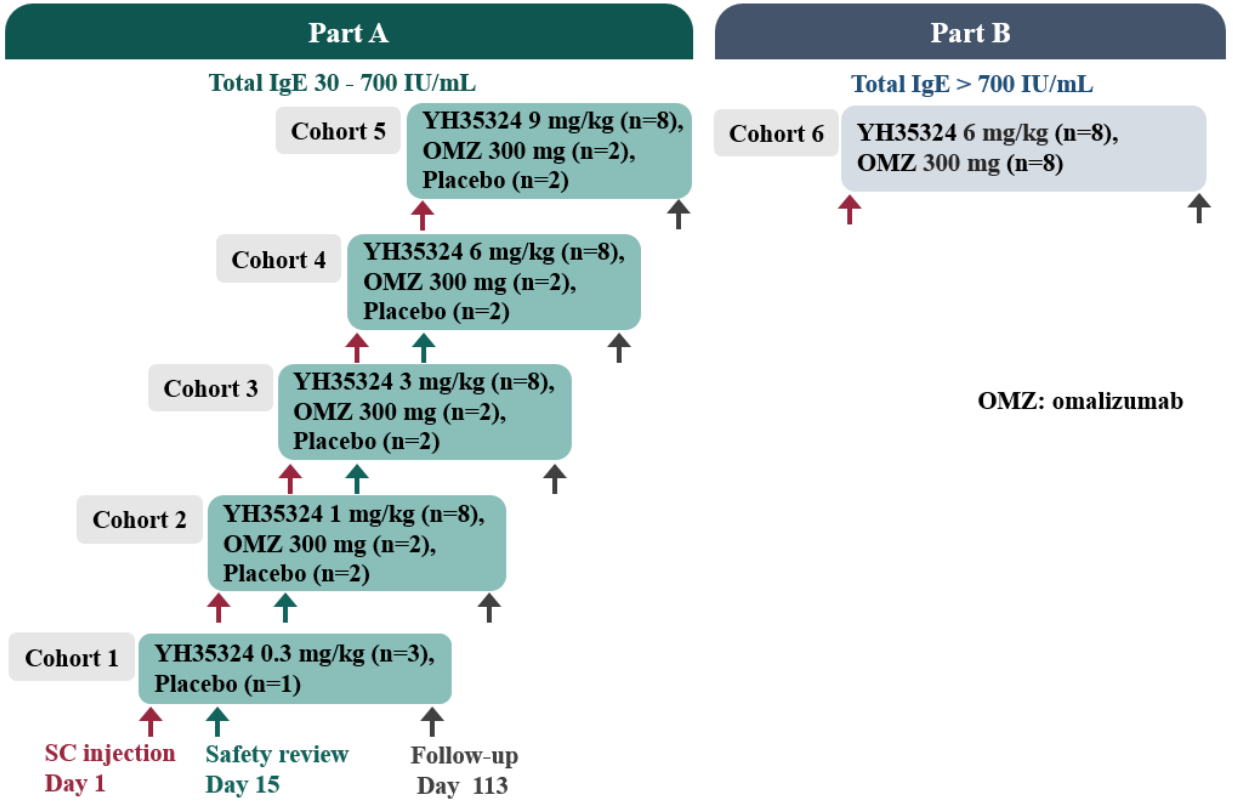
- YH35324 Safety and tolerability: Treatment-emergent adverse events

Secondary objectives and endpoints

- PK profile: Serum concentrations of YH35324
- PD profile: Change in serum free and total IgE levels

Exploratory objectives and endpoints

- PD for serum basophils: Change in FcεRI expression on basophil surface
- Inhibition of allergen hypersensitivity
  - Changes in allergen-induced skin prick weal response
  - Change in serum allergen-specific IgE levels
- Immunogenicity: Incidence of serum anti-YH35324 antibodies



ClinicalTrials.gov Identifier: NCT05061524

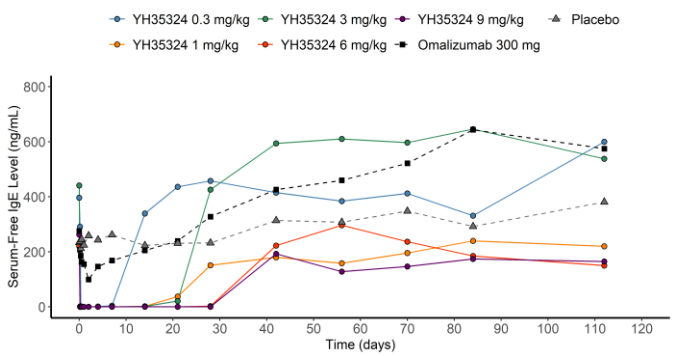
YH35324-101: Study Results

Overview of Treatment-Emergent Adverse Events (TEAEs)

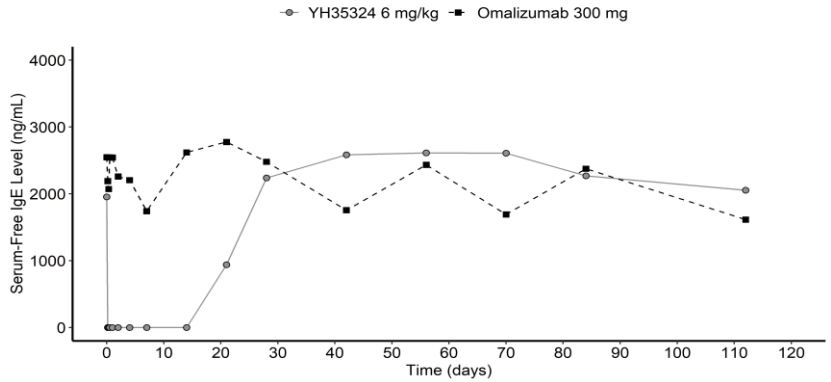
	YH35324 total (n=43)	Omalizumab 300 mg (N=16)	Placebo (N=9)
TEAEs	21 (48.8)	6 (37.5)	3 (33.3)
Drug-related TEAEs	4 (9.3)	5 (31.3)	1 (11.1)
Serious TEAEs or anaphylaxis discontinuation or death due to TEAEs	0 (0.0%)	0 (0.0%)	0 (0.0%)

Changes in Serum-Free IgE Level (Median) from Baseline after Treatment of YH35324, Placebo, or Omalizumab

Part A



Part B



This study demonstrated a favorable safety profile and the therapeutic potential of YH35324 which suppressed serum-free IgE levels in atopic subjects with allergic diseases such as allergic rhinitis, atopic dermatitis, food allergy, and urticaria.

Ye YM, Park JW, Kim SH, et al. Safety, Tolerability, Pharmacokinetics, and pharmacodynamics of YH35324, a novel Long-Acting High-Affinity IgETrap-Fc protein in subjects with Atopy: Results from the First-in-Human study. *Int Immunopharmacol*. 2024;130:111706.

YH35324-102: Study Design

Study Title: A Randomized, Double-Blind, Placebo/Active Controlled, Multiple Ascending Dose, Phase 1b Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Following Subcutaneous Injections of YH35324 in Atopic Healthy Subjects or Subjects with Mild Allergic Diseases

Target population

- Healthy subjects or subjects with mild allergic disease aged 19 - 55 years with atopy which is defined as having ≥ 1 positive result for inhalant or food allergens in a skin prick test and/or ImmunoCAP® specific IgE test, and serum total IgE levels of ≥ 30 IU/mL

Primary objective and endpoint

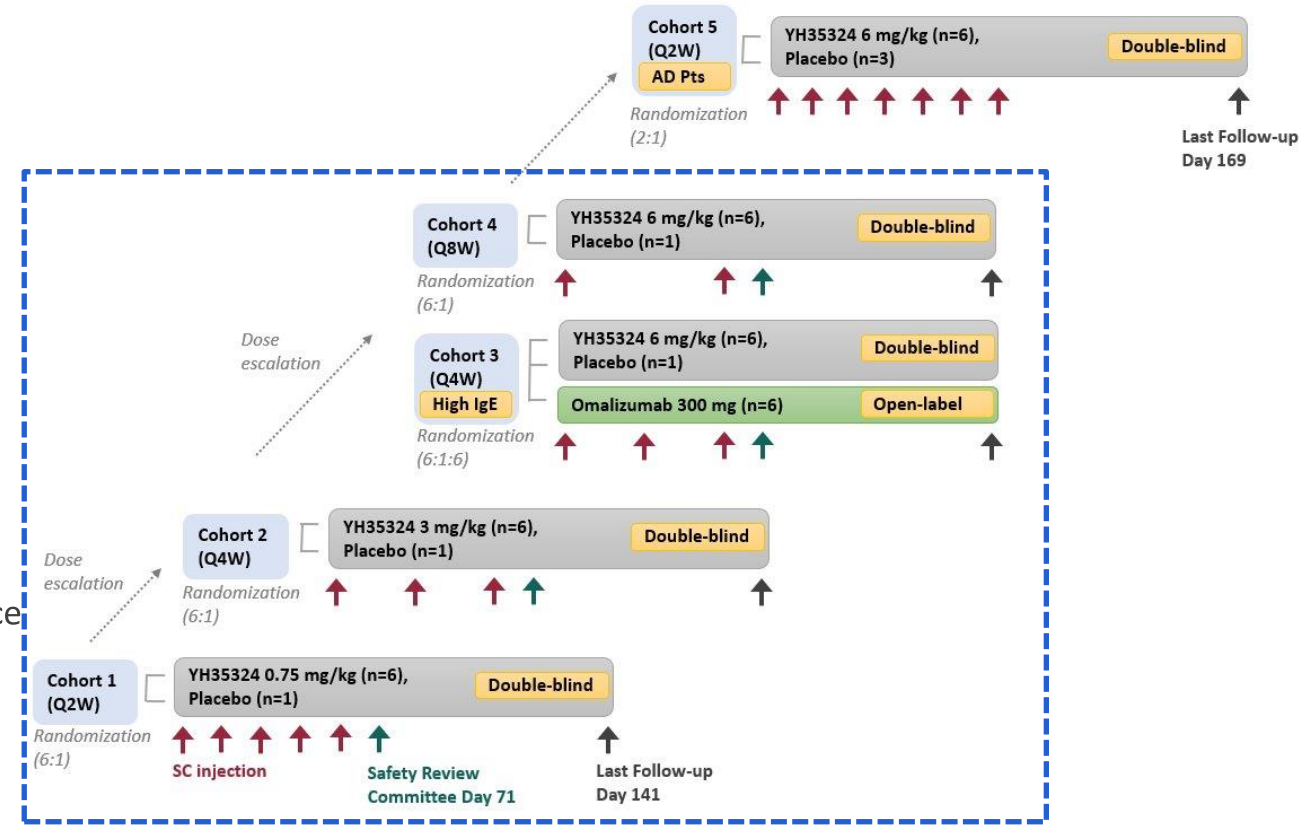
- YH35324 Safety and tolerability: TEAEs

Secondary objectives and endpoints

- PK profile: Serum concentrations of YH35324
- PD profile: Change in serum free- and total IgE levels

Exploratory objectives and endpoints

- PD for serum basophils: Change in FcεRI expression on basophil surface
- Inhibition of allergen hypersensitivity
  - Changes in allergen-induced skin prick weal response
  - Change in serum allergen specific IgE levels
- Immunogenicity: Incidence of serum anti-YH35324 antibodies



ClinicalTrials.gov Identifier: NCT05564221

YH35324-103: Study Design

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Study Title: A Randomized, Double-Blind, Placebo/Active Controlled, Single Dose, Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Following Subcutaneous Injections of YH35324 in Patients With Various Allergic Diseases

Primary objective and endpoint

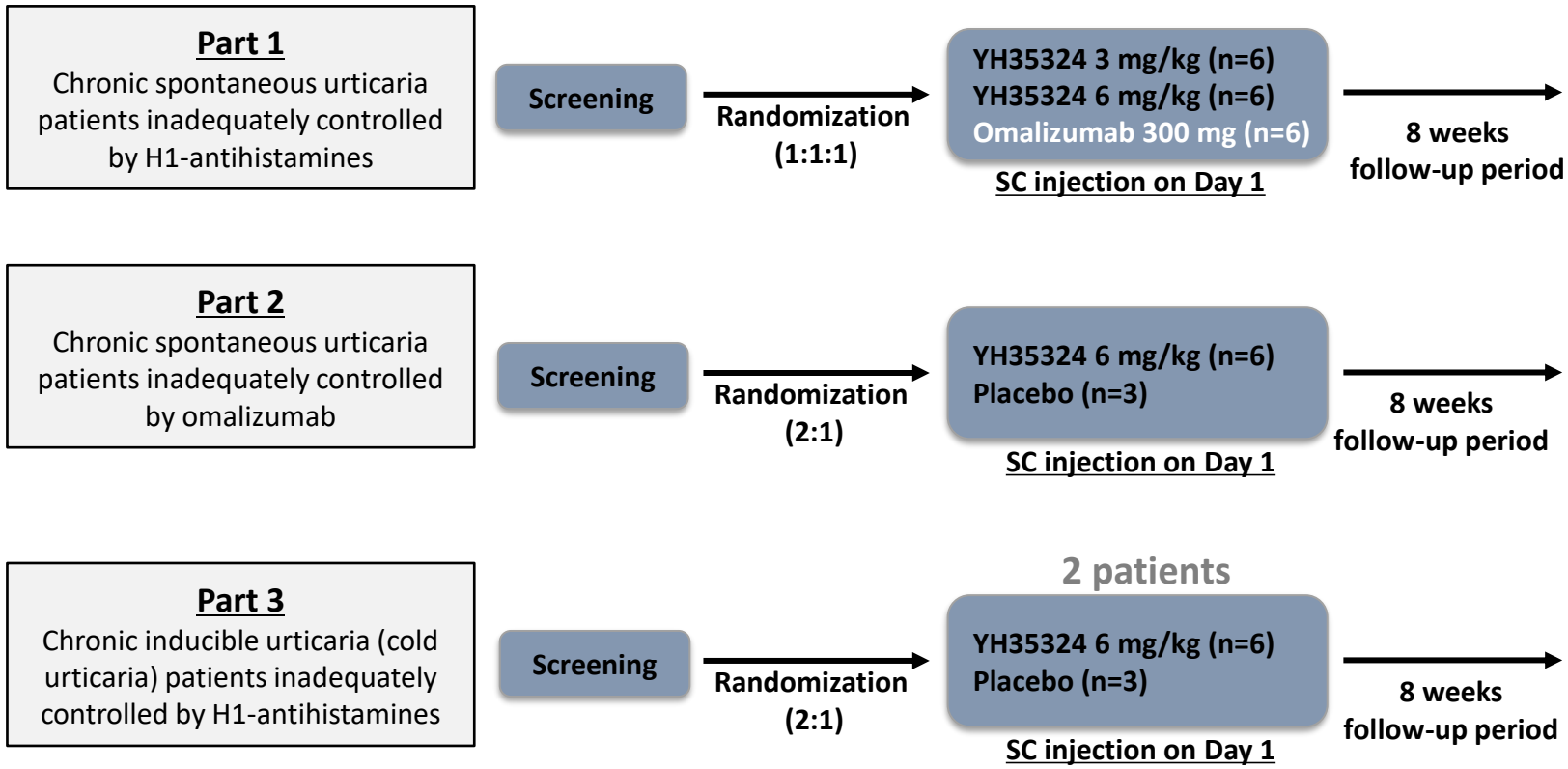
- Safety and tolerability: TEAEs

Secondary objectives and endpoints

- PD profile: Change in serum free IgE level

Exploratory objectives and endpoints

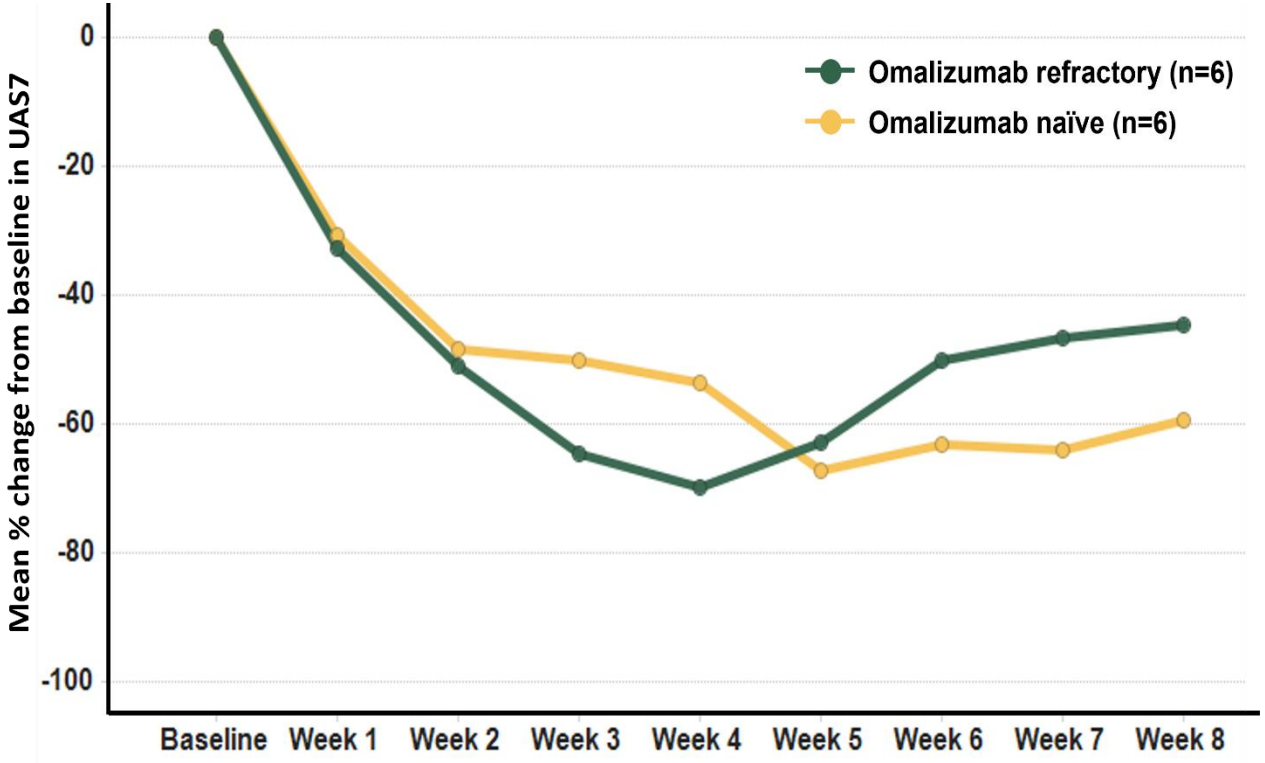
- Serum concentrations of YH35324
- Change in serum total IgE level, soluble FcƐRI level, MRGPRX2 level and FcεRI expression on basophil surface, basophil histamine release assay (BHRA)
- Urticaria control test, Use of rescue medication, Urticaria activity score (UAS7)
- Incidence of serum ADAs



ClinicalTrials.gov Identifier: NCT05960708

YH35324-103: Study Results

% Change from Baseline in UAS7 by Omalizumab Treatment History (Naïve vs. Refractory, Part 1/2 pooled analysis)



Symptom improvements following YH35324 treatment were comparable between **omalizumab-naïve and omalizumab-refractory patients**, suggesting that prior omalizumab exposure may not significantly influence therapeutic response to YH35324.

Lesigercept demonstrated potential clinical benefit in omalizumab-refractory patients, with no notable safety concerns observed compared to placebo.

The result was presented at the EAACI (European Academy of Allergy and Clinical Immunology) Annual Congress in June 2025.