HanAll Biopharma

Goldman Sachs Virtual Korea Corporate Day 2021

HANALL BIOPHARMA

February 2021

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Agenda

- Company overview
- HL161 (batoclimab) program
- HL036 (tanfanercept) program
- Summary

HANALL BIOPHARMA

- Vision: A global biopharmaceutical company focused on immunology and ophthalmology

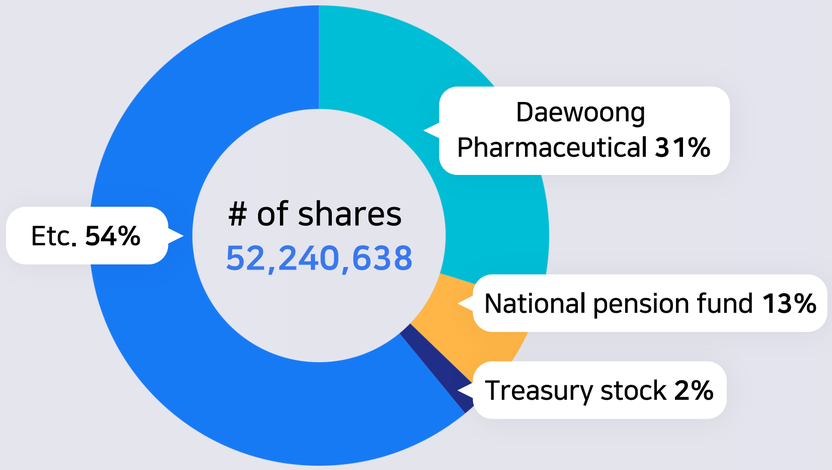
HANALL Overview

(As of Dec. 2020)

Incorporation date	11/20/1973	CEO	Seung-kook Park, Jae-chun Yoon
Date of listing	12/18/1989 (KOSPI market)	Employees	307
Main business	R&D / Production & selling ETC/OTC* drugs	Website	www.hanall.com
R&D	Innovative therapies (biologics & small molecules)	Headquarter	12 Bongeunsa-ro 114-gil, Gangnam-gu, Seoul, Korea

* ETC (Ethical the counter) / OTC (Over the counter)

Shareholders (as of Dec. 2020)



Major facilities

- HanAll Pharmaceutical International (HPI), Inc. in Rockville, MD, USA
- Boston office planned in 2021

- Biologics lab in Suwon
- Small molecules lab in Seoul
- Pharmaceutical factory in Daejeon

Transforming to Global Innovative Biopharmaceutical Company

Foundation of R&D labs

'02 Chemical lab in Seoul

'07 Biologic lab in Suwon

'08 HPI in MD, USA

Collaborations

nautilus biotech

'07 Licensed 3 drugs from French-based biotech, Nautilus

'09 Acquiring patents of protein engineering technologies

Developments & License-out deals

ROIVANT SCIENCES

IMMUNOVANT

HARBOUR BIOMED

Global clinical trials from 2010

'17 Licensing agreement with Roivant & Harbour BioMed

R&D focused biopharmaceutical company

Promising candidates
- HL161 in Ph2 and HL036 in Ph3

Expanding global R&D presence

R&D Foundation

- HanAll, as a team, believes in science, takes risks for innovation, learns from mistakes, and humbly serves patients.

Antibody therapeutics

- HanAll has developed know-how to find optimal antibodies for specific targets
- Screening from both the phage-display library and transgenic animals
- Well-established in vitro and in vivo assays to come up with optimized therapeutics

Protein therapeutics

- “Resistein™”, acquired protein engineering technologies from Nautilus biotech in 2009
- Molecular engineering to enhance affinity to targets and resistance to protease degradation
- The accumulated knowledge of production working with different external collaborators

HL143 (belerofon)
Protease-resistant interferon-α

HL032 (vitatropin)
Developed as human GH (growth hormone) oral tablet

R&D Pipeline

	Project code	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Partners
Immunology	HL036 (tanfanercept)	Dry eye disease (DED)					(US) (China)	DAEWOONG PHARMACEUTICAL CO.,LTD. / HARBOUR BIOMED (China)
	HL161 (batoclimab)	Myasthenia gravis (MG)					(US) (China)	IMMUNOVANT (US/EU) / HARBOUR BIOMED (China)
		Thyroid Eye Disease (TED)				(US) (China)		IMMUNOVANT (US/EU) / HARBOUR BIOMED (China)
		Warm autoimmune hemolytic anemia (WAIHA)				(US)		IMMUNOVANT (US/EU)
		Neuromyelitis optica (NMO)				(China)		HARBOUR BIOMED (China)
		Immune thrombocytopenia (ITP)				(China)		HARBOUR BIOMED (China)
	HL189 (tanfanercept)	Non-Infectious uveitis (NIU)						
Oncology	HL186 /HL187	Immuno-oncology						DAEWOONG PHARMACEUTICAL CO.,LTD.

(Clinical trials sites)

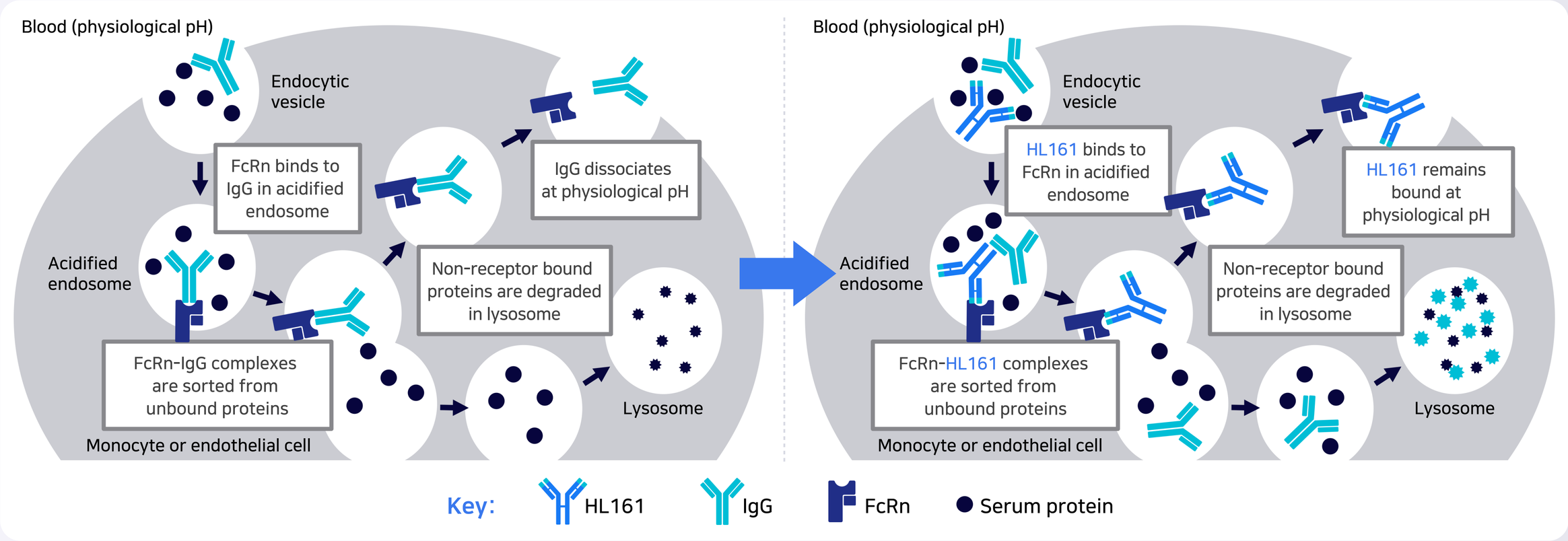
HL161 (batoclimab) for IgG-mediated autoimmune diseases

HL161 (batoclimab)

SC injectable fully human anti-FcRn antibody

HL161 (anti-FcRn Antibody)

- **HL161:** a fully human monoclonal antibody for the treatment of IgG-mediated autoimmune diseases
- **Indication:** IgG-mediated autoimmune diseases including MG (Myasthenia Gravis) and TED (Thyroid Eye Disease)
- **Mechanism of action:** HL161 binds to FcRn to block recycling of IgG, leading to elimination of IgG antibodies in the lysosome



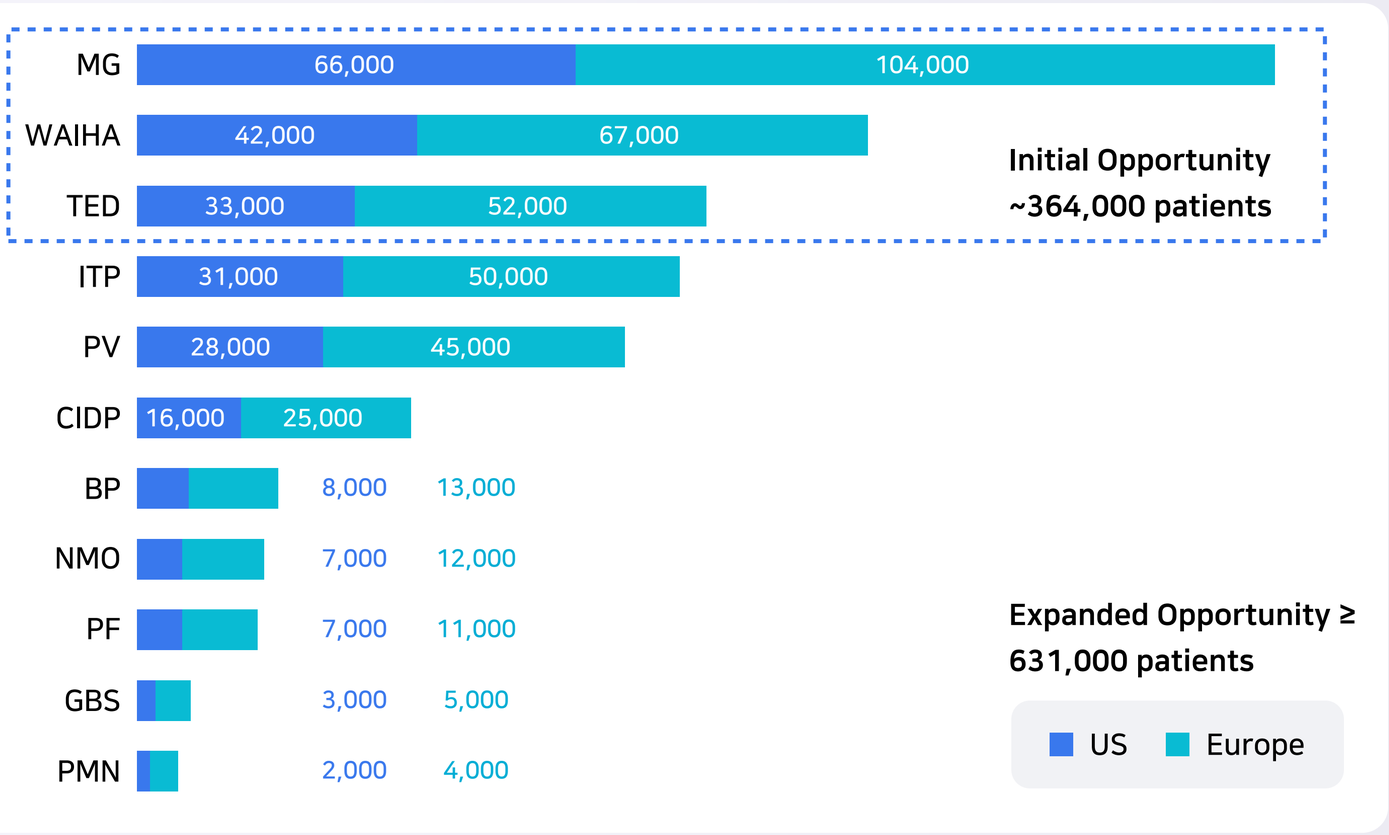
- FcRn is Fc receptor that has a role of transcytosis and IgG recycling responsible for the long half-life of IgG in the bloodstream.
- By inhibiting FcRn-IgG interaction, IgG will undergo degradation by lysosomes.

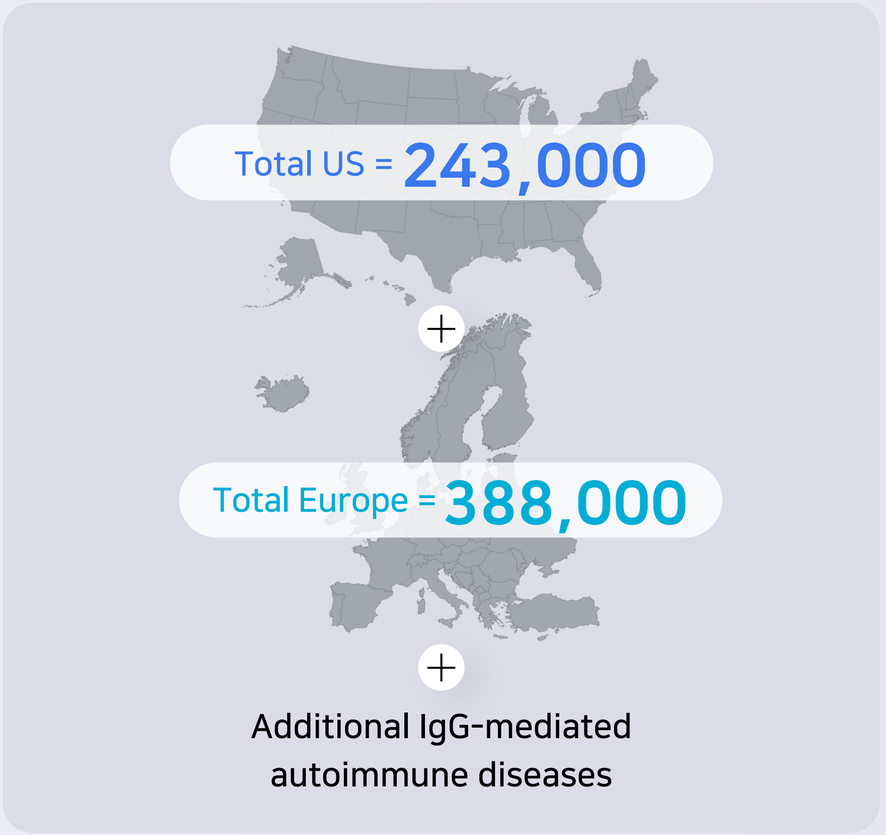
(Source: Immunovant Presentation)

Broad Range of Potential Applications for anti-FcRn Mechanism (US/EU)

- **FcRn inhibition lowers IgG levels, suggesting utility in multiple autoimmune diseases**

An illustrative list of autoimmune diseases driven by pathogenic IgG and their estimated prevalence (2019)



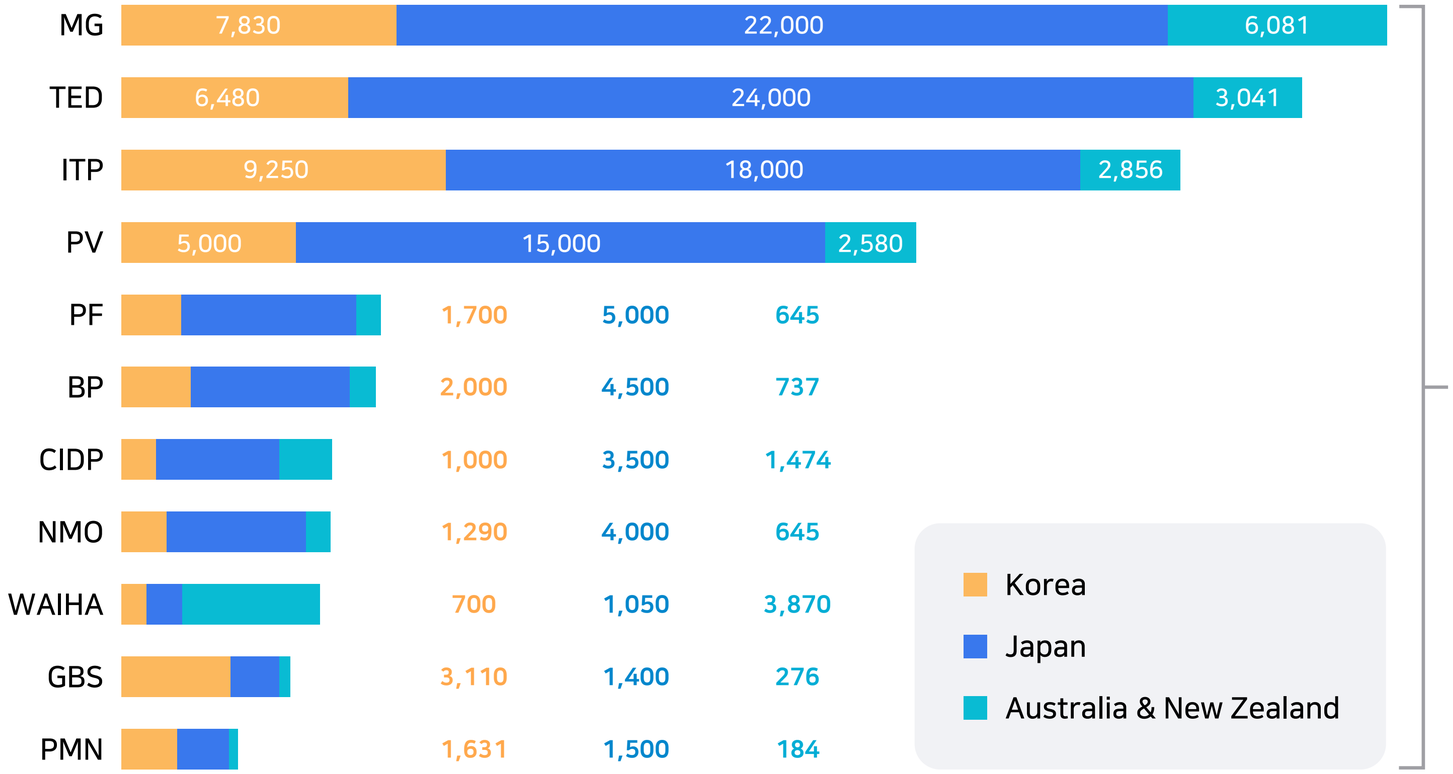


MG: Myasthenia Gravis, WAIHA: Warm Autoimmune Hemolytic Anemia, TED: Thyroid Eye Disease, ITP: Idiopathic Thrombocytopenic Purpura,
BP: Bullous Pemphigoid, NMO: Neuromyelitis Optica, PF: Pemphigus Foliaceus, GBS: Guillain-Barre Syndrome, PMN: PLA2R+ Membranous Nephropathy

(Source: Immunovant Presentation)

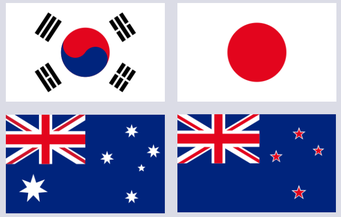
Market Opportunity in Japan, Korea, Australia, and New Zealand (HanAll's Territory)

- **The estimated prevalence of target indications in KR, JP, AUS, and NZ**



Potential opportunity
162,332 Patients

Total US =
243,000



Total =
162,332

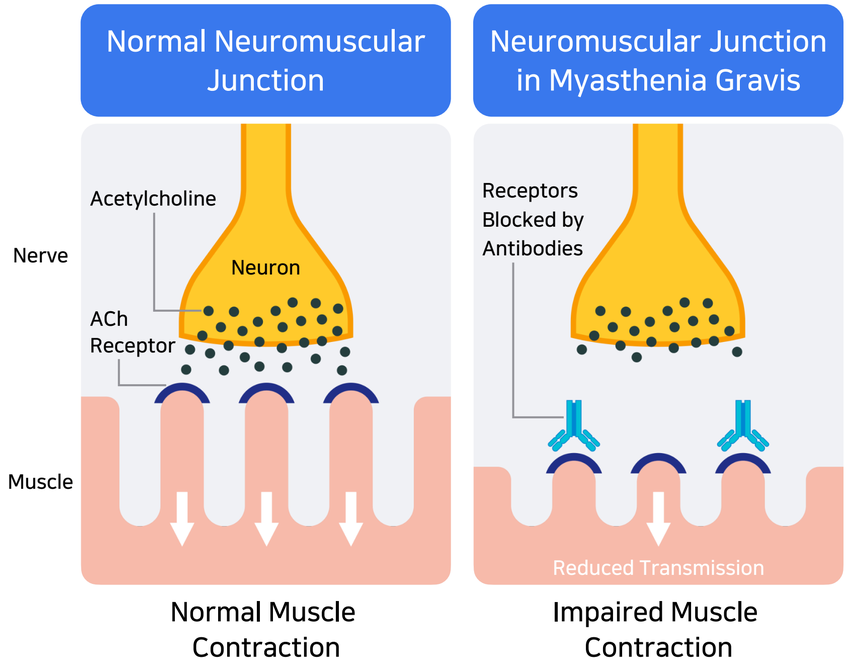
IgG mediated auto-immune disease in KR, JP, AUS and NZ
> 60% of US patients

MG: Myasthenia Gravis, **WAIHA**: Warm Autoimmune Hemolytic Anemia, **TED**: Thyroid Eye Disease, ITP: Idiopathic Thrombocytopenic Purpura, **PV**: Pemphigus vulgaris, CIDP: Chronic Inflammatory Demyelinating Polyradiculoneuropathy, **BP**: Bullous Pemphigoid, NMO: Neuromyelitis Optica, **PF**: Pemphigus Foliaceus, **GBS**: Guillain-Barre Syndrome, **PMN**: PLA2R+ Membranous Nephropathy

(Source: MHLW Japan bigdata, related journals, Immunovant Presentation)

Myasthenia Gravis Overview

- Rare autoimmune disorder affecting an estimated 66,000 people in the US[1]
- Characterized by the weakness of voluntary muscles including ocular, facial, oropharyngeal, limb, and respiratory muscles[1]
- 15-20% of MG patients will experience at least one myasthenic crisis over their lifetimes, a potentially life-threatening acute complication[2]
- Disease caused by autoantibodies targeting the neuromuscular junction[1]
- ~93% of patients have an identified autoantibody[1]
  - Anti-acetylcholine receptor (AChR) antibodies (~85%)
  - Anti-muscle-specific tyrosine kinase (MuSK) antibodies (~8%)

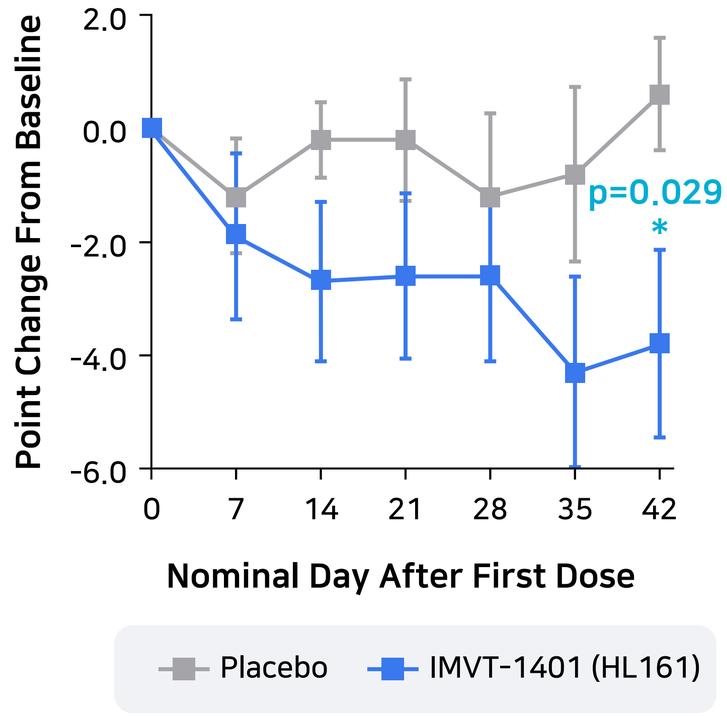


1. Meriggioli M.N. and Sanders D.B. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? Expert Review Clinical Immunology, 2012
2. Sudulagunta S.R., et al. Refractory myasthenia gravis - clinical profile, comorbidities and response to rituximab. German Medical Science, 2016

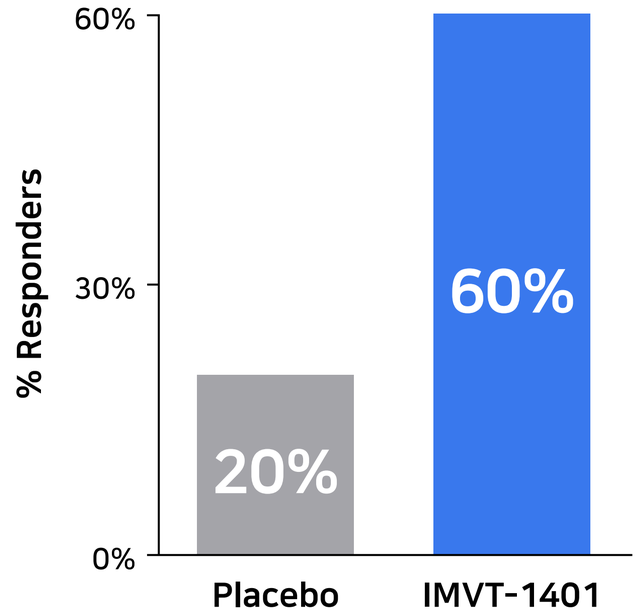
(Source: Immunovant Presentation)

Encouraging Topline Results of Phase 2 in Patients with MG

MG-ADL* Change From Baseline[1]



MG-ADL % Responders[2], Day 42



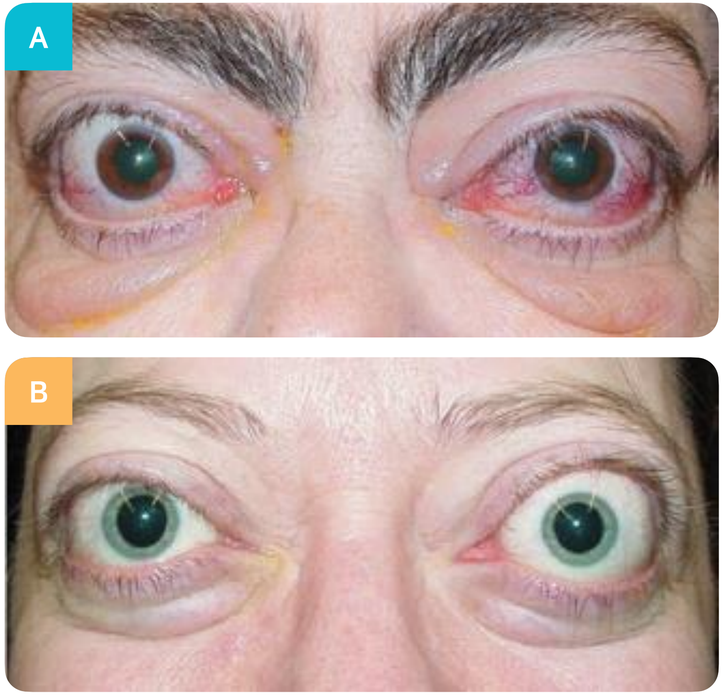
*MG-ADL (Myasthenia Gravis Activities of Daily Living): A validated FDA regulatory endpoint comprised of 8 items reflecting ocular, bulbar, respiratory, and limb symptoms and their impact on function

1. IMVT-1401 group represents pooled data from 10 patients receiving either 340 mg or 680 mg IMVT-1401 weekly. *Indicates ANCOVA p = 0.029. Error bars represent standard error of the mean.
2. MG-ADL responders defined as patients showing ≥ 2-point improvement.

(Source: Immunovant Presentation)

Thyroid Eye Disease (TED)

- **Also called Graves' orbitopathy or ophthalmopathy (GO)**
- **15,000 - 20,000 patients with active TED in the United States per year**
- **Clinical features[1]:**
  - Eye bulging ("Proptosis")
  - Eye pain
  - Double vision ("Diplopia")
  - Light sensitivity
- **Can be sight - threatening[2]**
- **Caused by autoantibodies that activate cell types present in tissues surrounding the eye[2]**
- **Close temporal relationship with Graves' disease**



Bahn, 2010
Figure 1. Patients with Thyroid Eye Disease
Panel A shows a 59-year-old woman with excess proptosis, moderate eyelid edema, and erythema with moderate eyelid retraction affecting all four eyelids. Conjunctival chemosis (edema) and erythema with bilateral edema of the caruncles, with prolapse of the right caruncle, are evident. Panel B shows a 40-year old woman with excess proptosis, minimal bilateral injection, and chemosis with slight erythema of the eyelids. She also had evidence, on slit-lamp examination, of moderate superior limbic keratoconjunctivitis.

(Source: Immunovant Presentation)

1. Davies T. and Burch H.B. Clinical features and diagnosis of Graves' orbitopathy (ophthalmopathy), UpToDate, 2018
2. McAlinden C. An overview of thyroid eye disease. Eye and Vision, 2014

Positive Proof of Concept for HL161 (batoclimab) in Thyroid Eye Disease

Positive clinical results after 6 weeks of treatment

- 65% mean reduction in total IgG from baseline to end of treatment
- 57% of patients improved by ≥ 2 points on clinical activity score (CAS)
- 43% of patients were both proptosis responders* and CAS responders**
- 67% of patients with baseline diplopia saw an improvement in diplopia

Observed to be safe and generally well-tolerated

- Subcutaneous injection
- No serious adverse events (SAEs) were reported
- No withdrawals due to adverse events (AEs)
- All reported AEs were mild or moderate
- No headaches were reported

* Proptosis responders improved ≥ 2mm in study eye without significant deterioration in fellow eye
** CAS responders achieved a total CAS score of 0 or 1

(Source: Immunovant Presentation)

Immunovant Recently Announced a Voluntary Pause of Dosing of Its Ongoing Trials

- On Feb. 2, Immunovant announced a voluntary pause of dosing in its ongoing clinical trials for IMVT-1401 (HL161) due to elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease (TED)

- Based on preliminary, unblinded data from about 40 patients through week 12, mean LDL cholesterol at week 12 was increased by approximately 65% in the 680mg dose group, by approximately 40% in the 340mg dose group, and did not increase in the control group
- Unblinded analysis of the data from ASCEND GO-2 trial remains ongoing.

- A further update on current and future indications and timelines in the second quarter of calendar year 2021.

HL036 (tanfanercept) for dry eye disease

Tanfanercept

Anti-TNF molecule optimized for topical use

Dry Eye Disease

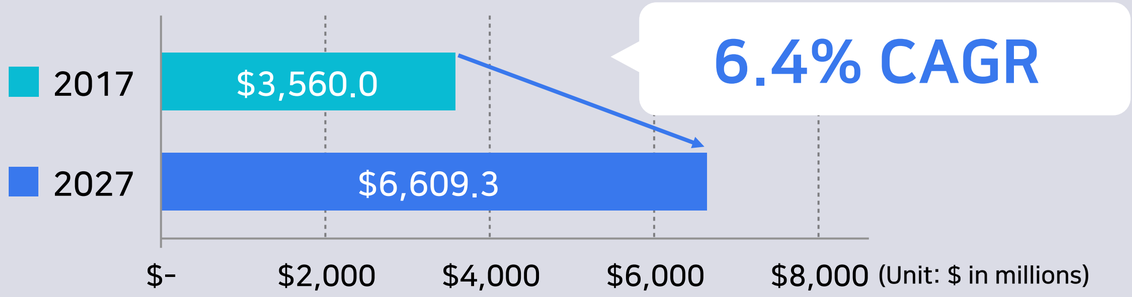
Dry eye disease:

Dry eye occurs when the eye glands do not produce enough tears or when the tears evaporate too quickly. Symptoms of dry eye range from subtle but constant eye irritation to significant inflammation and even scarring of the front the surface of the eye.

Stats:

Dry eye disease is a common eye disorder that affects more than 6% of the population worldwide.

The global market for dry eye disease treatment



(Source : Future Market Insights 2017)

- **North American market accounts for 70% of the global market, which is about $2.5 billion.**
- **Current FDA-approved products:**
  - Restasis (Allergan) – Sales: $1.2 billion (2019)
  - Xiidra (Novartis) – Sales: $388 million (2018)
  - Eysuvis(Kala) – approved in Oct. 2020

→ Only limited ETCs are approved and they have limited efficacy with side effects such as burning sensation in eyes, that lead to low adherence rates.

→ There is still a significant unmet need and high demand for new treatments with better efficacy.

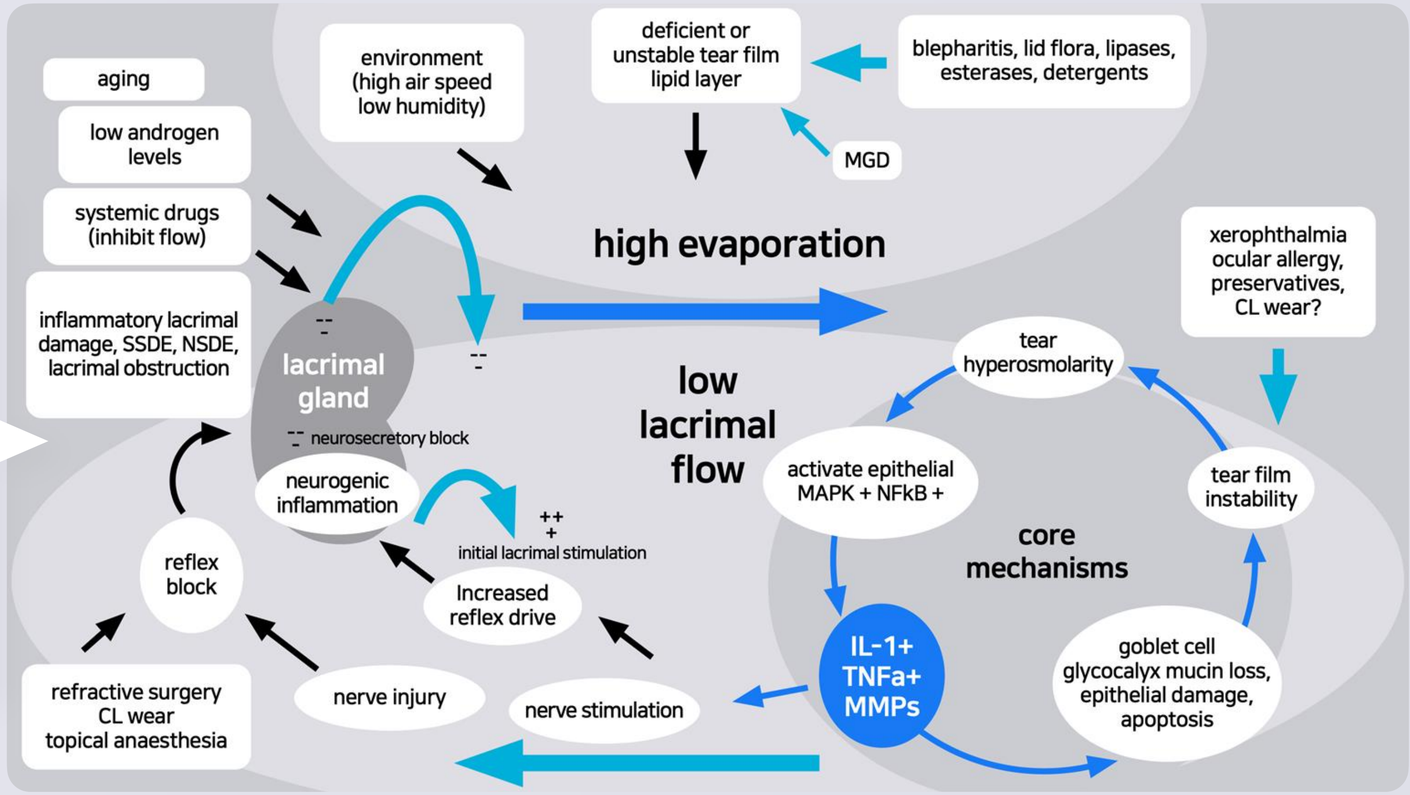
Main Pathology of Dry Eye Disease

Dry Dey Disease (DED)

- “Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyper-osmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.”
  (DEWS II (2017))

Vicious Cycle of DED

1. High evaporation or Low lacrimal flow
2. Tear hyperosmolarity
3. Activation of epithelial MAPK/NF$_k$B
4. Proinflammatory cytokines (IL-1, IL-6, TNF)
5. Epithelial damage and apoptosis → mucin loss
6. Tear film instability



Optician (2017) https://www.opticianonline.net/

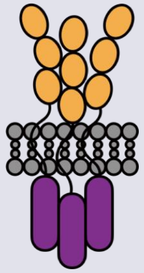
Concept of HL036 Ophthalmic Solution (anti-TNF Biologic)

Fragmentation

Molecular Engineering
(Resistein™ technology)

Formulation

TNFR-1 → Anti-TNF Peptide → Tanfanercept → Eye drops



19kDa

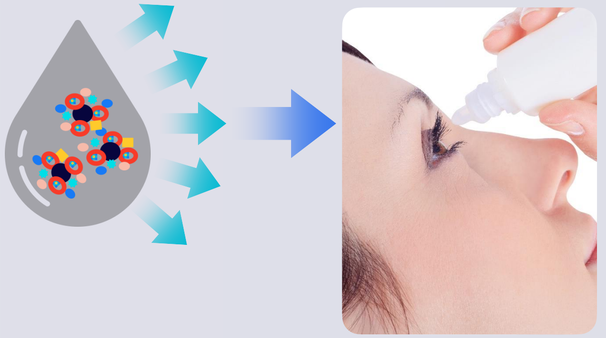
19kDa

[By utilizing Resistein technology]

① Optimized size

② Strong TNF neutralizing activity

③ Resistant to proteases



Molecular characteristics and proposed application of HL036

- **Enhanced ocular penetration** from small size (19 kDa)
- **High stability** (6 months in RT, >2 yrs in a refrigerator)
- **Strong neutralizing activity against TNFα**
- **Negligible systemic exposure**

Target inflammatory eye diseases

- Dry eye, Uveitis, and other inflammatory eye diseases
- Minimal systemic adverse effects

Phase 3-1 (VELOS-2) Trial Design in Dry Eye Disease

Phase 3-1 (VELOS-2) Overview

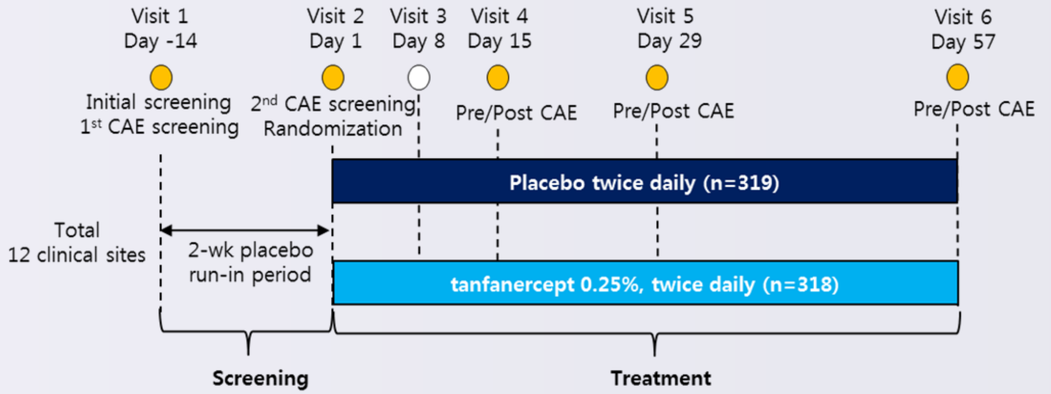
- Multicenter, randomized, double-masked and placebo-controlled study evaluating the Efficacy and Safety of 0.25% HL036 ophthalmic solution compared to placebo

- Study group: 1) HL036 0.25% ophthalmic solution (318 patients)
  2) Placebo (319 patients)

- Duration: 10 weeks (2 weeks screening + 8 weeks treatment)

- Primary endpoints: [Sign] Inferior corneal staining score (ICSS)
  [Symptom] Ocular discomfort score (ODS)

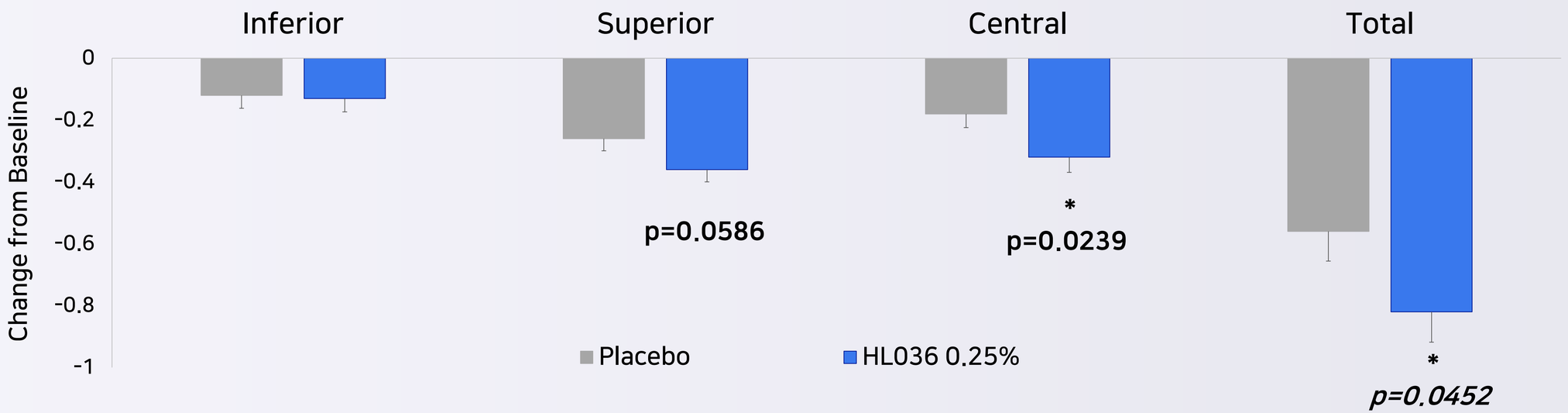
- Mar. 2019 - FPFV, Jan. 2020 - Topline data



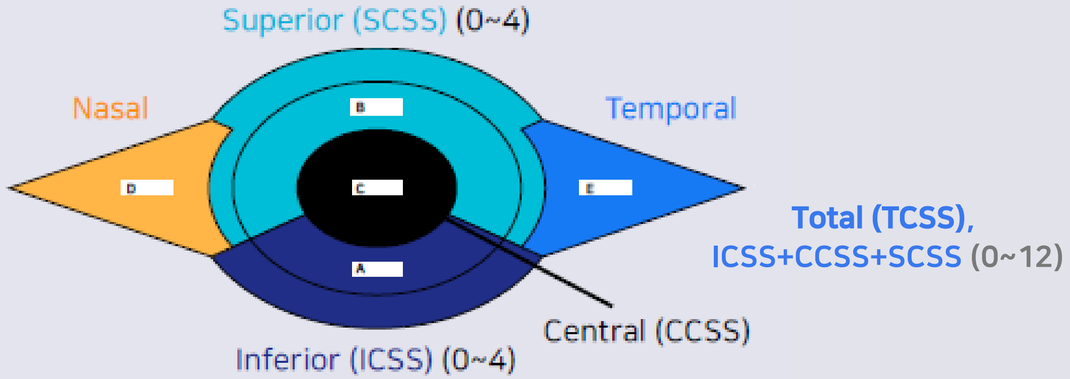
Sign Improvement Observed in Phase 3-1 (VELOS-2) Study

- **Change of Corneal Staining Score (CSS) from Baseline at week 8**

(N=319/318)



Ora Calibra® Corneal Staining Score (CSS)

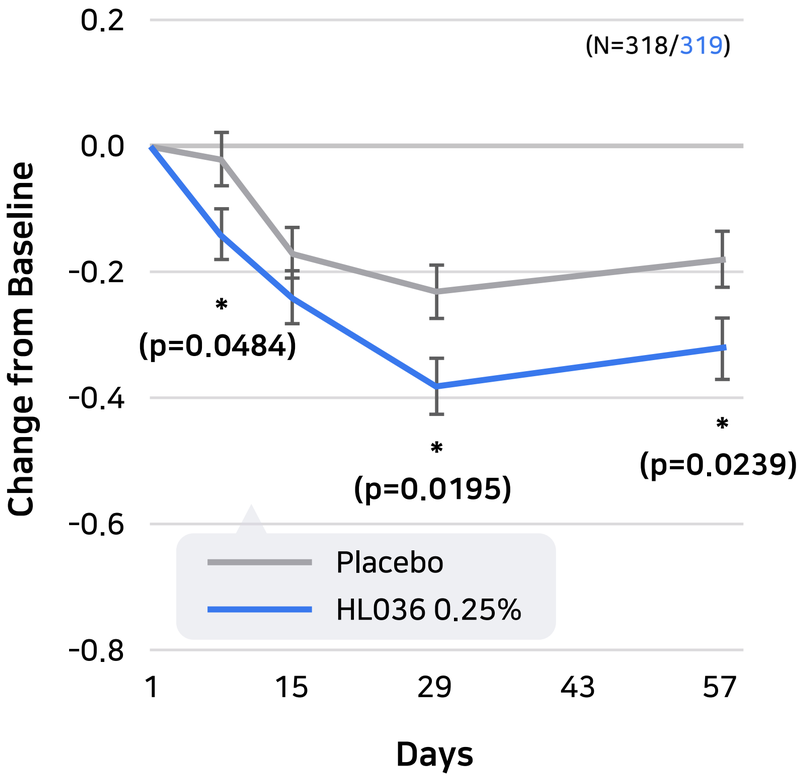


- Data analysis with ITT Population
- P-value by two-sided t-test; *, p <0.05, Italic letter, p value by ANCOVA model

0	None	no staining
1	Trace	occasional
2	Mild	countable
3	Moderate	uncountable, but not confluent
4	Severe	confluent

Subgroup Analysis in Central Corneal SS according to Baseline Severity

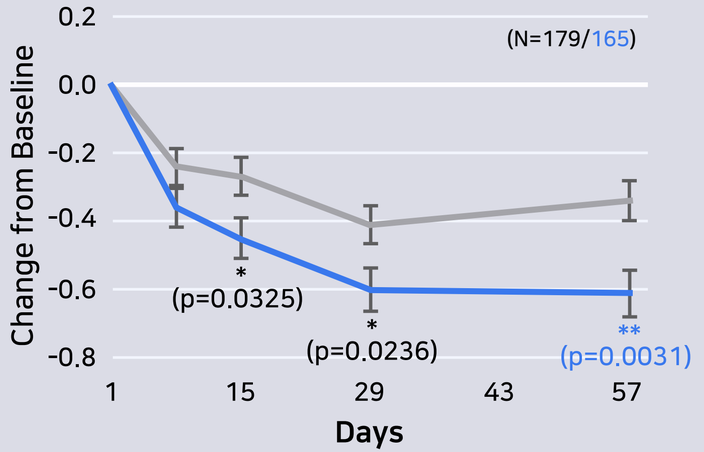
CCSS (ITT)
(Any CSS* ≥2)



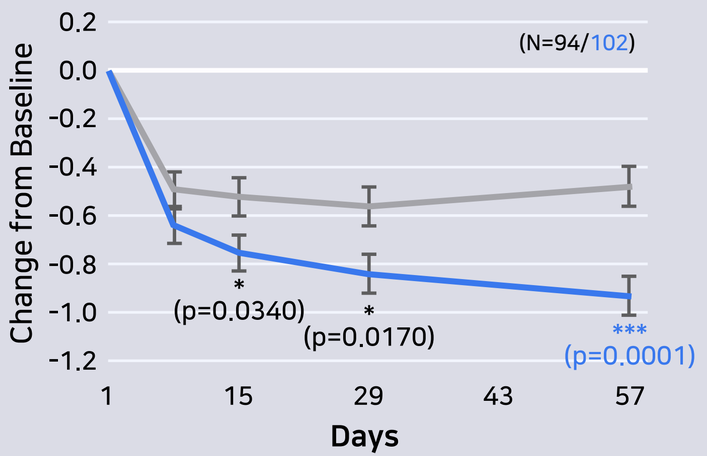
*Any CSS: CSS at least one region

p-value by two-sided t-test; * , p<0.05; ** , p<0.01; ***, p<0.001

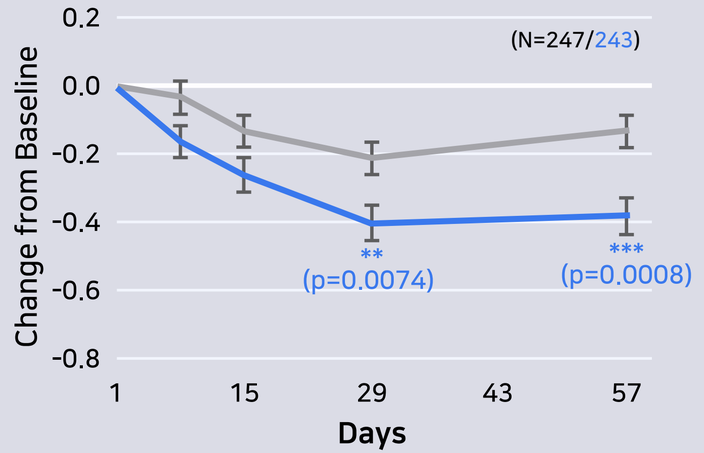
Sub group #1 (TCSS baseline ≥5)



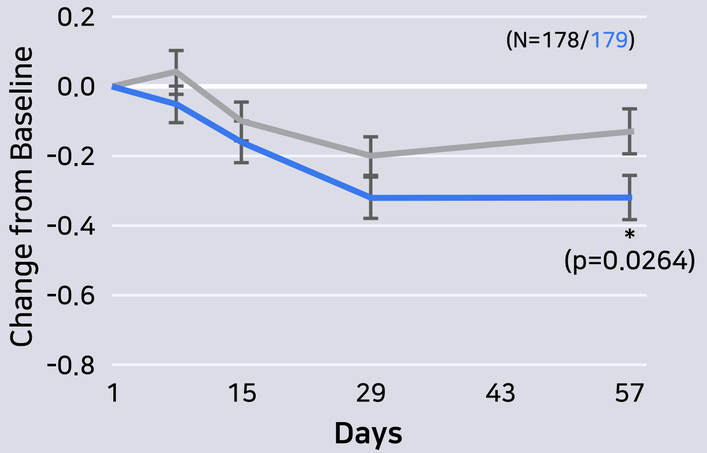
Sub group #2 (CCSS baseline ≥2)



Sub group #3 (Schirmer's baseline ≤7)



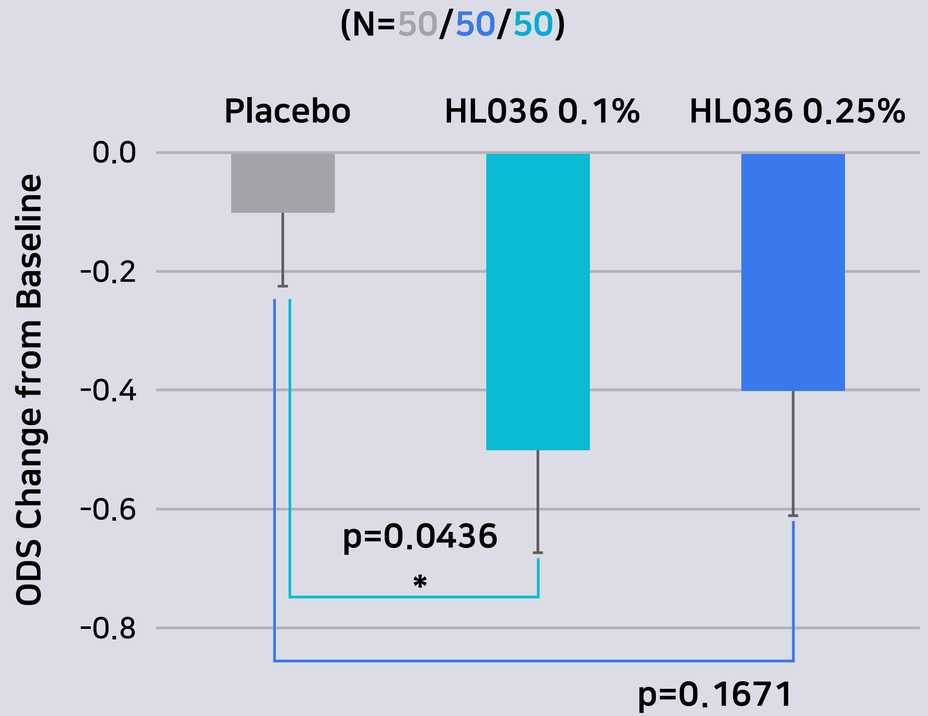
Sub group #4 (ODS baseline ≥3)



Symptom Improvement in Phase 2 (VELOS-1) and Phase 3-1 (VELOS-2) Studies

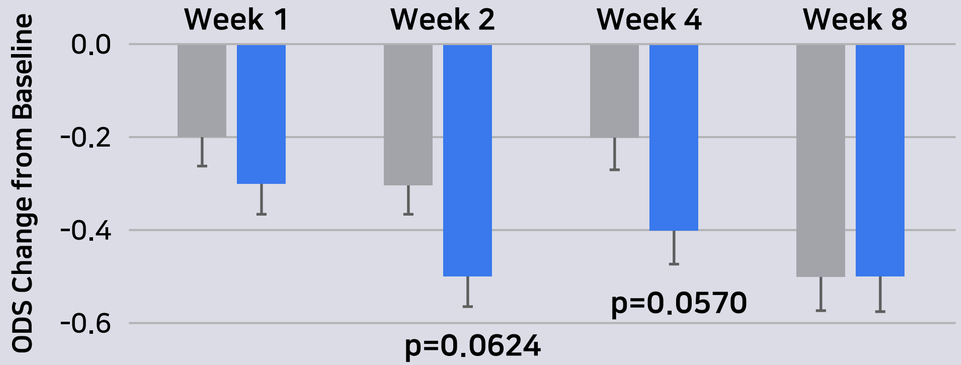
Phase 2 (VELOS-1 Study)

Ocular Discomfort Score (ODS) at week 8

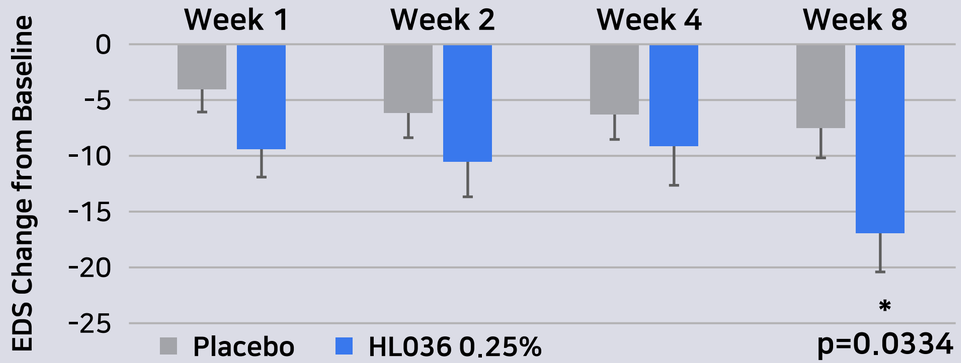


Phase 3-1 (VELOS-2 Study)

Ocular Discomfort Score (ODS), ITT (N=319/318)



Eye Dryness Score (EDS), Subgroup ATU ≤1M* (N=75/63)



*ATU<1month: artificial tear use within 1 month prior to enrollment
P-value by two-sided t-test; *, p <0.05

What We Learned from Phase 3-1 (VELOS-2) Study

Dry Eye Disease

- **Heterogeneous patient populations:**
  - different pathologies mixed (aqueous deficiency vs. high evaporative)
- **Lack of severity correlation between signs and symptoms**
- **Control group** shows strong placebo effects

Tanfanercept

- **Fast and sustained anti-inflammatory effect in central cornea**
- **More treatment effects on more severe patients both in sign and symptom**
- **Favorable drop comfort score** comparable to artificial tear

Clinical Operational Challenge

- The devil is in the detail **(art of CRO management)**
- Pros and cons of using **various efficacy measuring tests**
- Study design/methodology **tailored to Tanfanercept and its MOA**

Next Clinical Development Plan (Tentative)

	-	VELOS-1	VELOS-2	VELOS-3*	VELOS-4*
Stage	**Phase 1**	**Phase 2**	**Phase 3-1**	**Phase 3-2**	**Phase 3-3**
Purpose	Safety and Tolerability	Efficacy in Sign & Symptom	Efficacy in Sign & Symptom	Efficacy in Sign	Efficacy in Symptom
Country	South Korea	US	US	US	
Timeline	Completed in 2016	Completed in 2018	Completed in 2020	Planned to **initiate in H2 2021**	Planned to **initiate in 2021/22**
Subjects	Healthy volunteers	Mild-to-Moderate Sign & Symptom Patients	Mild-to-Moderate Sign & Symptom Patients	**Moderate-to-Severe Sign** Patients	**Moderate-to-Severe Symptom** Patients
Groups	HL036 0.05%, n=8 HL036 0.5%, n=8 Placebo, n=4	HL036 0.1%, n=50 HL036 0.25%, n=50 Placebo, n=50	HL036 0.25%, n=318 Placebo, n=319	HL036 0.25%, n=XX Placebo, n=XX	HL036 0.25%, n=XX Placebo, n=XX
Treatment	BID for a day	BID for 2-week Screening and 8-week Treatment			
Primary Endpoints	Ocular examinations, Systemic examinations	ΔICSS for sign ΔODS for symptom	ΔICSS, CAE for sign ΔODS for symptom	**ΔCCSS for sign** ΔEDS for symptom	**ΔEDS for symptom** ΔCCSS for sign
Secondary Endpoints	HL036 PK in serum	ΔCCSS, ΔSCSS, ΔTCSS, Conjunctival redness, Schirmer's test, TFBUT, ΔEDS, ΔOSDI, ΔOD&4S	ΔICSS, ΔCCSS, ΔSCSS, ΔTCSS, Conjunctival redness, Schirmer's test, TFBUT, ΔEDS, ΔOSDI, OD&4S	ΔICSS, ΔSCSS, ΔTCSS, Conjunctival redness, Schirmer's test, TFBUT, ΔODS, ΔOSDI, OD&4S	

*Tentative plan

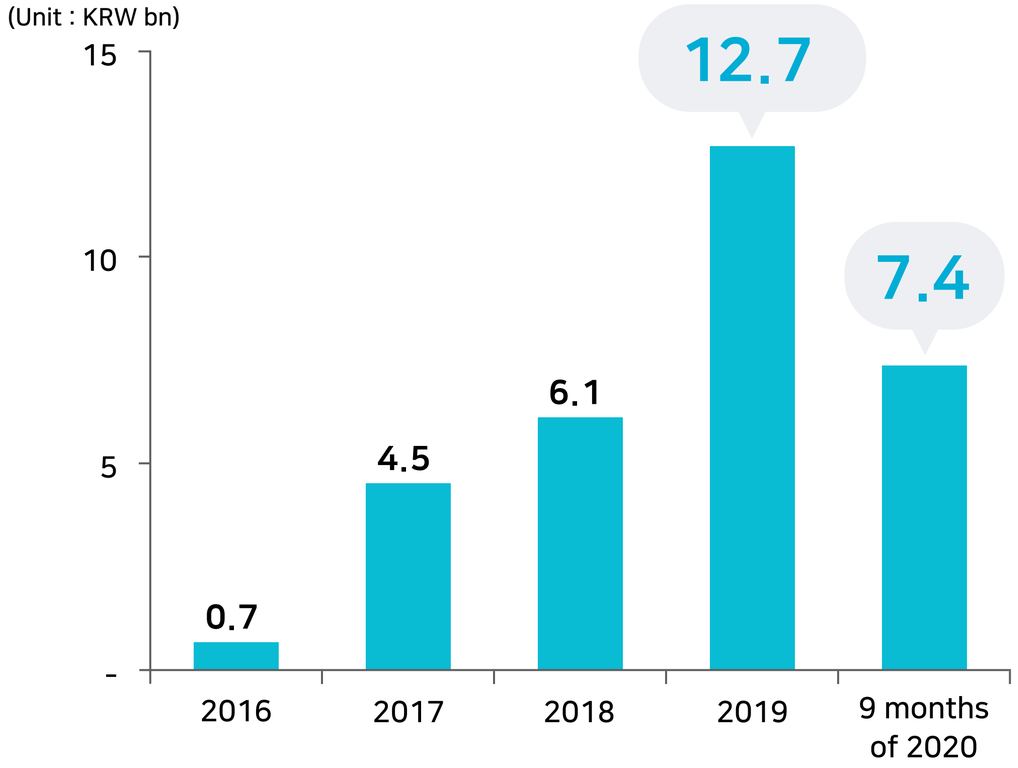
HanAll Completed a Type-C Meeting with FDA for Next DED Trials

- The study design of the two proposed Phase 3 studies (VELOS-3 and VELOS-4) appears acceptable
- Evaluating a ”sign” and a “symptom” in separate clinical trials with different defined patient populations is acceptable
- The proposed dry eye sign and symptom primary endpoints are acceptable

HanAll: A Global, Innovative Biopharmaceutical Company

Revenue from milestone payments is steadily growing

R&D revenues



Received & Expected milestone payments

2019

- **Harbour BioMed**
  - HL036 (Dry eye disease) in Q1 2019
  - HL161 (Autoimmune diseases) in Q3 2019
- **Roivant (Immunovant)**
  - HL161 (Autoimmune diseases) in Q2 2019

2020

- **Harbour BioMed**
  - HL161 (Autoimmune diseases) in Q2 2020

2021 (Expected)

- **Harbour BioMed**
  - HL036 (Dry eye disease) in 2021
  - HL161 (Autoimmune diseases) in 2021
- **Roivant (Immunovant)**
  - HL161 (Autoimmune diseases) in 2021

Note: HanAll recognize an upfront and milestone payments from Immunovant for approximately 5.8 years until commercialization

HanAll Highlights: virtuous cycle

Steady existing business

- Constantly generating profitable operating margin
- Organic cash inflow into R&D investments

Accumulated R&D expertise

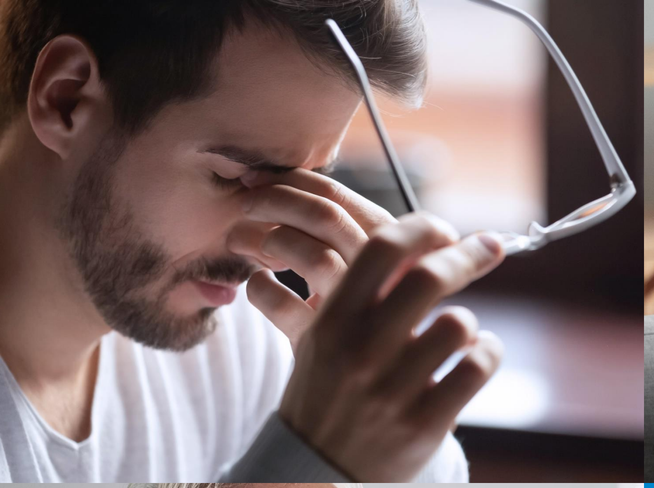
- Discovering and developing biologics for 14+ years
- Open innovation and global collaboration network

Promising pipeline

- HL161: a front runner in the FcRn antibody class
- HL036: promising in dry eye disease and other indications

Successful partnerships

- Partnerships with Daewoong, Immunovant, and Harbour BioMed
- Expected milestone payments from the partners




Thank You

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