

IR Presentation



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HanAll is growing and transforming into global innovative biopharma

R&D-focused company with 47-years of pharmaceutical business

Experience of 10+ year of global research and development

Late-stage biologics - HL036 in Phase 3 & HL161 in Phase 2

Partnerships with Roivant, Harbour BioMed, and Daewoong

Profitability - Sales and profits from existing in-market products

Sound balance sheet - Net cash approximately \$80M as of H1 2020

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3

Company Introduction



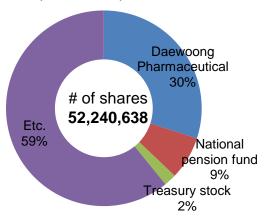
Vision: A global biopharmaceutical company focused on immunology and ophthalmology

HANALL Overview
(As of Mar. 2020)

Incorporation date	11/20/1973	CEO	Seung-kook Park, Jae-chun Yoon
Date of listing	12/18/1989 (KOSPI market)	Employees	313 (incl. R&D 38)
Main business	Main business R&D / Production & selling ETC/OTC* drugs		www.hanall.com
R&D	Innovative therapies (biologics & small molecules)	Headquarters	12 Bongeunsa-ro 114-gil, Gangnam-gu, Seoul, Korea

^{*} ETC (Ethical the counter) / OTC (Over the counter)

Shareholders (as of Dec. 2019)



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



47 Years of Pharmaceutical Business





Production

- Chemical medicines manufacturing since 1973
- Can produce tablets, capsules, ointments, ampules, and vials at facilities in Daejeon, South Korea



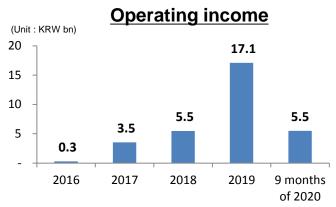
Sales & Marketing

- Sales and marketing experience for 40+ years
- · Launched a number of new drugs in Korea
- A sales force of 110 experienced medical representatives



Profitable existing business

- Approximately 15% of margin from legacy business
- Funding R&D expenses without cash burn
- Continue to expect to have profits due to milestones



R&D investments

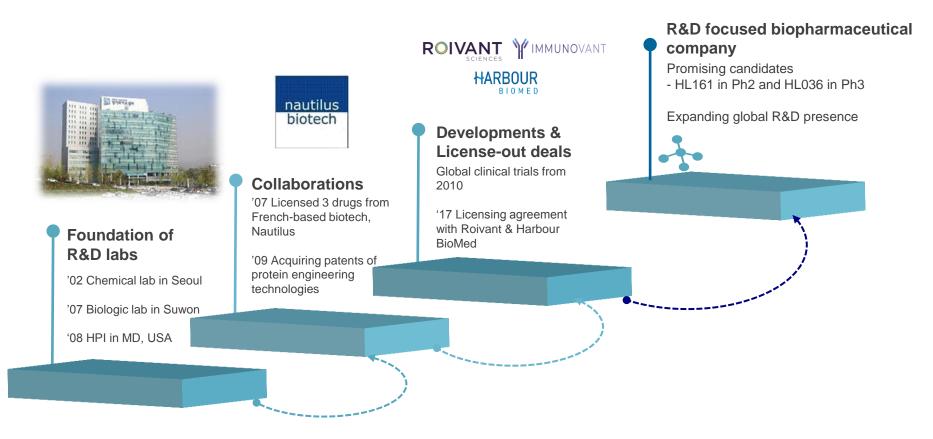


■ R&D expenses ■ Capitalized*

* HanAll capitalize R&D expenses from Phase 3

Transforming to Global Innovative Biopharmaceutical Company





R&D Foundation



Antibody therapeutics

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

Protein therapeutics

- "ResisteinTM", acquired protein engineering technologies from Nautilus biotech in 2009
- Molecular engineering to enhance affinity to targets and resistance to protease degradation
- Accumulated knowledge of production working with different external collaborators

HL143 (belerofon)

- Protease-resistant interferon-α

HL032 (vitatrophin)

- Developed as human GH (growth hormone) oral tablet

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

Licensing Agreements with Immunovant & Harbour BioMed



Immunovant

- Completed in Dec. 2017 ROIVANT
- Rights to develop, manufacture, and commercialize HL161
 in the United States, Canada, Mexico, the European Union, the United
 Kingdom, Switzerland, Latin America, the Middle East, and North Africa
- \$502.5 million in total, including an upfront payment of \$30m, milestone payments of \$452.5m, and \$20m for R&D
- Royalties: mid-single digits to mid-teens on net sales of HL161

Harbour BioMed

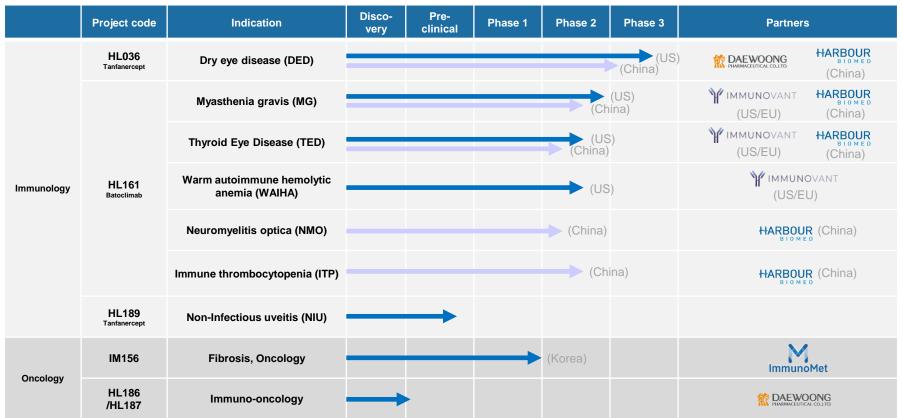
- Completed in Sep. 2017 HARBOU
- Rights to develop, manufacture, and commercialize HL036 and HL161 in Greater China (including Hong Kong, Macau and Taiwan)
- **\$81 million** in total, including an upfront payment of \$4m and milestone payments of \$77m
- Royalties: high-single digits to mid-teens on net sales of both HL036 and HL161



R&D Pipeline



9



(Clinical trials sites)

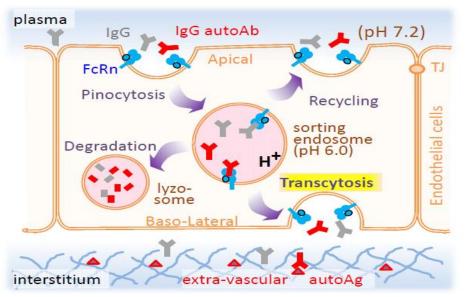
HL161 (batoclimab) for IgG-mediated autoimmune diseases

Batoclimab

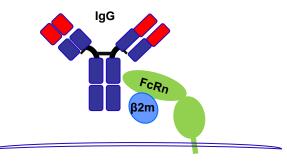
HL161 (anti-FcRn Antibody)



- HL161: a fully human monoclonal antibody for treatment of IgG-mediated autoimmune diseases
- Indications: MG (Myasthenia Gravis), GO (Graves' Ophthalmopathy), and other IgG-mediated autoimmune diseases
- Mechanism of action: HL161 binds to FcRn to block recycling of IgG, leading to elimination of IgG antibodies in lysosome



Dr. Borza, D.B..

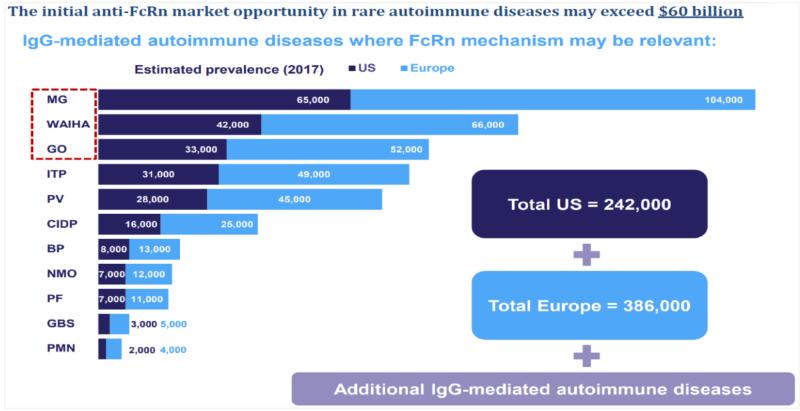


*IgG(Immunoglobulin G): a type of antibody

- 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.

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



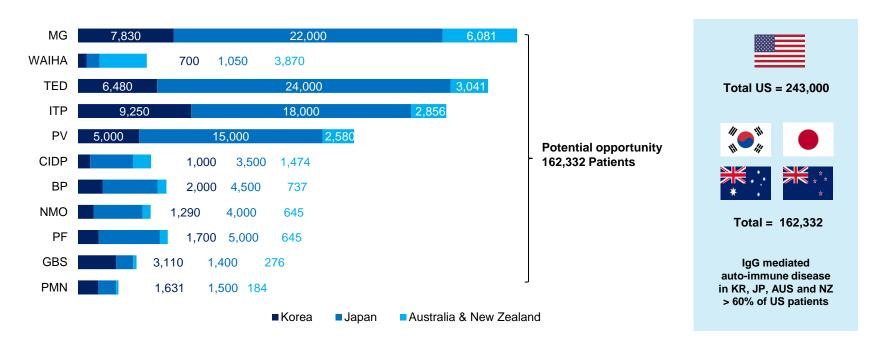


MG: Myasthenia Gravis, WAIHA: Warm Autoimmune Hemolytic Anemia, GO: Graves' Ophthalmopathy, ITP: Idiopathic Thrombocytopenic Purpura, BP: Bullous Pemphigoid, NMO: Neuromyelitis Optica, PF: Pemphigus Foliaceus, GBS: Guillain-Barre Syndrome, PMN: PLA2R+ Membranous Nephropathy

(Source: Chardan)

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

Estimated prevalence of target indications in KR, JP, AUS and NZ



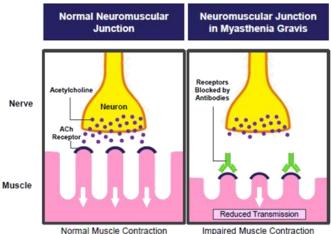
MG: Myasthenia Gravis, WAIHA: Warm Autoimmune Hemolytic Anemia, TED: Thyroid Eye Disease, ITP: Idiopathic Thrombocytopenic Purpura, PV: Pemphigus vulgaris, CIDP: Chronic Inflammatory Demyelinating Polyradiculoneuropathy, BP: Bullous Pemphigoid, NMO: Neuromyelitis Optica, PF: Pemphigus Foliaceus, GBS: 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 US¹
- Characterized by weakness of voluntary muscles including ocular, facial, oropharyngeal, limb, and respiratory muscles¹
- 15-20% of MG patients will experience at least one myasthenic crisis over their lifetimes, a potentially life-threatening acute complication²
- Disease caused by autoantibodies targeting the neuromuscular junction¹
- ~93% of patients have an identified autoantibody¹
 - Anti-acetylcholine receptor (AChR) antibodies (~85%)
 - Anti-muscle-specific tyrosine kinase (MuSK) antibodies (~8%)





[Patient with Ptosis]

[Source: Immunovant Presentation]

Meriggioli M.N. and Sanders D.B. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? Expert Review Clinical Immunology, 2012

Sudulagunta S.R., et al. Refractory myasthenia gravis – clinical profile, comorbidities and response to rituximab. German Medical Science, 2016

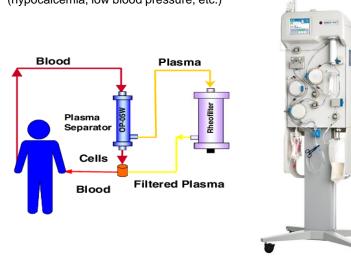
Current Treatments



- High-dose steroids or immunosuppressants are used to manage symptoms of autoimmune diseases.
- In emergencies, such as in acute lupus flare, plasmapheresis or IVIg is used for rapid management of symptoms.

Plasmapheresis

- A process that separates the blood cells from the plasma, removing antibodies, and returning blood back into the body
- Cons: High cost (~\$100,000) and severe side effects (hypocalcemia, low blood pressure, etc.)



Intravenous Immunoglobulin (IVIg)

- An IV infusion therapy which is prepared from the blood of thousands of donors to dilute autoantibodies and relieve symptoms
- <u>Cons:</u> High cost (~\$200,000/cycle), limited efficacy, and severe side effects (cerebromeningitis, acute renal failure, shock, etc.)





Best- & First-in-class Features of HL161 & anti-FcRn Competitors



16

Company	HANALI HARBOUR BIOMED IMMUNOVANT	argenx		ALEXION'	Momenta Johnson
Product	HL161/IMVT-1401 / HBM9161 (Batoclimab)	ARGX-113	UCB7665	SYNT001	M281
(INN)		(Efgartigimod)	(Rozanolixizumab)	(Orilanolimab)	(Nipocalimab)
Modality	Fully human IgG1	Mutated Fc fragment (NR)	Humanized IgG4	Humanized IgG4	Fully human IgG1
(homology) ^{b)}	(92%/98%)		(87%/76%)	(79%/81%)	(91%/94%)
Administration route & dose	SC injection.	IV infusion,	SC infusion,	IV infusion,	IV infusion.
	340mg/680mg, QW	10mg/kg, QW	7mg/kg, QW	10~30mg/kg, QW	30~60mg/kg, Q2W
Adverse events	No significant AEs	No significant AEs	More frequent headache	More frequent headache	No significant AEs
Stage / Indication ^{c)}	P2 in MG/GO/ WAIHA/NMOSD/ITP	P3 in MG/ITP P2 in PV/CIDP	P3 in MG/ITP P2 in CIDP	P2 in WAIHA/MG	P2 in MG/WAIHA/HDFN

a) All competitive assessments based on publicly available information (publications, company presentation, clinical trial registries, etc.)

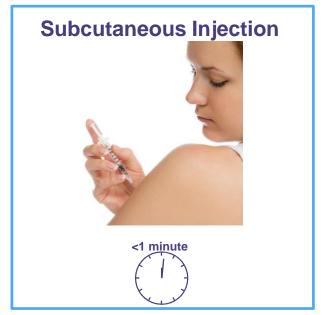
b) Based on the amino acid sequence comparison of variable domains with the human germline sequence (V_H %/V_I %)

^{c)} Indication: MG, myasthenia gravis; GO, Grave's ophthalmopathy; NMO, neuromyelitis optica; ITP, idiopathic thrombocytopenic purpura; PV, pemphigus vulgaris; CIPD, chronic inflammatory demyelinating polyneuropathy; WAIHA, warm autoimmune hemolytic anemia; HDFN, hemolytic disease of the fetus and newborn

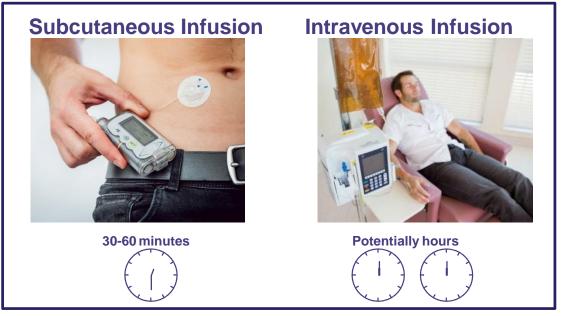
First Anti-FcRn Antibody by Convenient Subcutaneous Injection







Alternative Approaches



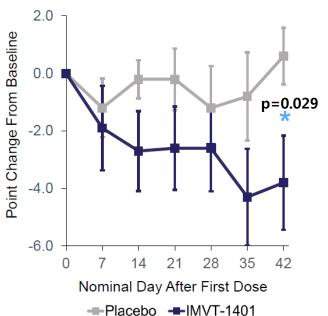
Potential simple fixed dose subcutaneous anti-FcRn antibody for the treatment of IgG-mediated autoimmune diseases

[Source: Immunovant Presentation]

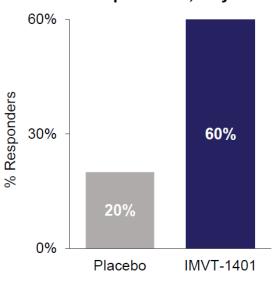
Encouraging Topline Results of Phase 2 in Patients with MG



MG-ADL* Change From Baseline¹



MG-ADL % Responders², Day 42



[Source: Immunovant Presentation]

^{*}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

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.

MG-ADL responders defined as patients showing ≥ 2-point improvement.

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 features¹:
 - Eye bulging ("Proptosis")
 - Eye pain
 - Double vision ("Diplopia")
 - Light sensitivity
- Can be sight-threatening²
- Caused by autoantibodies that activate cell types present in tissues surrounding the eye²
- 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.

Davies T. and Burch H.B. Clinical features and diagnosis of Graves' orbitopathy (ophthalmopathy), UpToDate, 2018

McAlinden C. An overview of thyroid eye disease. Eye and Vision, 2014

Positive Proof of Concept for Batoclimab in Thyroid Eye Disease



Positive clinical results after 6 weeks of treatment	Observed to be safe and generally well-tolerated
 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 	 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

Development Timeline of Batoclimab





HL036 (tanfanercept) for dry eye disease

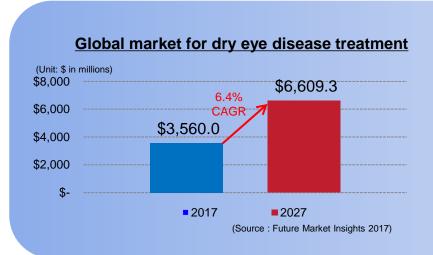
Tanfanercept

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 surface of the eye.
- **Stats:** Dry eye disease is a common eye disorder that affects more than 6% of the population worldwide.





- 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 2020 Oct
 - → 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

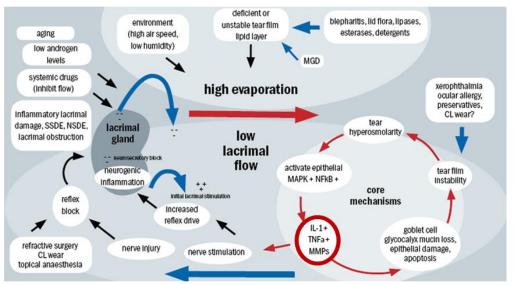


> Dry Dey Disease (DED)

 "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

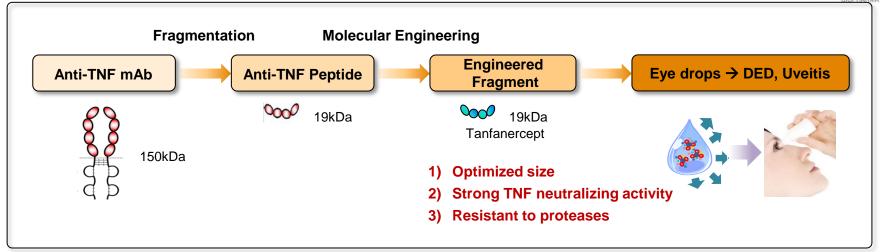
- > 1) High evaporation or Low lacrimal flow
 - 2 Tear hyperosmolarity
 - 3 Activation of epithelial MAPK/NFKB
 - 4 Proinflammatory cytokines (IL-1, IL-6, TNF)
 - ⑤ Epithelial damage and apoptosis → mucin loss
 - ⑥ Tear film instability



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

Concept of HL036 Ophthalmic Solution (anti-TNF Biologic)





- Molecular characteristics and proposed application of HL036
 - ✓ Enhanced ocular penetration from small size (19 kDa)
 - √ High stability (6 months in RT, >2 yrs in 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

Next Clinical Development Plan (Tentative)



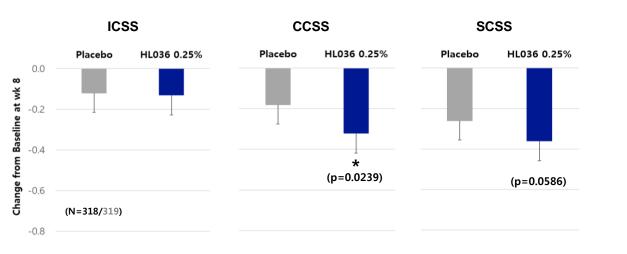
	-	VELOS-1	VELOS-2	VELOS-3*	VELOS-4*
Stage	Phase 1	Phase 2	Phase 3-1		
Purpose	Safety and Tolerability	Efficacy in Sign & Symptom	Efficacy in Sign & Symptom		
Country	South Korea	US	US		
Timeline	Completed in 2016	Completed in 2018	Completed in 2020		
Subjects	Healthy volunteers	Mild-to-Moderate Sign & Symptom Patients	Mild-to-Moderate Sign & 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		
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		
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		

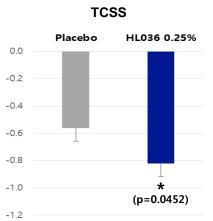
^{*} Tentative plan

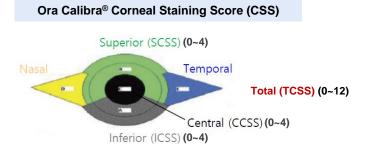
Sign Improvement Observed in VELOS-2 Study



Change of Corneal Staining Score (CSS) from Baseline at Week 8



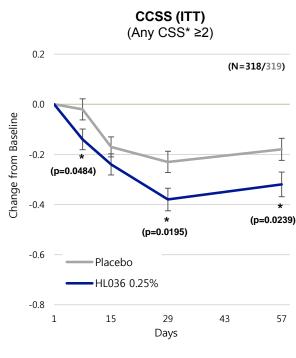




0	None	no staining
1	Trace	occasional
2	Mild	countable
3	Moderate	uncountable, but not confluent
4	Severe	confluent

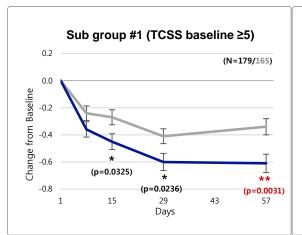
Subgroup Analysis in Central Corneal SS according to Baseline Severity

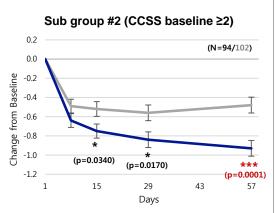


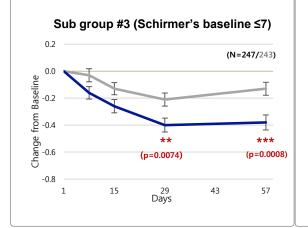


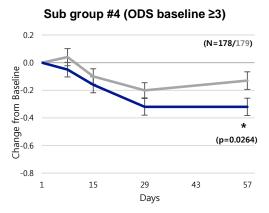
*Any CSS: CSS at least one region

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









Symptom Improvement Observed in VELOS-1 and VELOS-2 Study

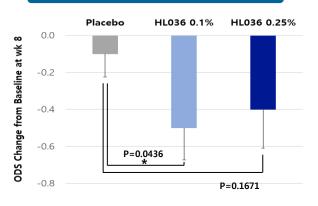


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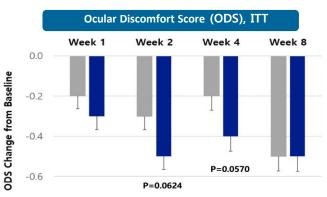
(N=50/50/50)

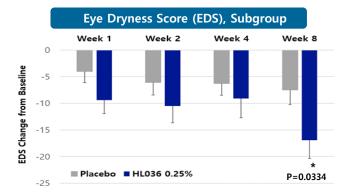
Ocular Discomfort Score (ODS) at week 8



Phase 3 (VELOS-2 Study)

(N=319/318)





What We Learned from 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)

					HA
	-	VELOS-1	VELOS-2	VELOS-3*	VELOS-4*
Stage	Phase 1	Phase 2	Phase 3-1	Phase 3-2	Phase 3-3
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Country	South Korea	US	US	U	S
Timeline	Completed in 2016	Completed in 2018	Completed in 2020	Planning to initia	ate in 2021/2022
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
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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

Upcoming Milestones

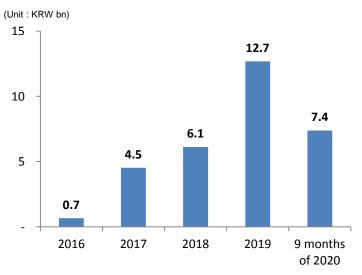


Timing	Event	Collaboration with
Jan. 2020	HL036, topline results of Phase 3-1 (VELOS-2) in dry eye disease	₩ 대응제약
Mar. 2020	HL161 (IVMT-1401), topline data of Phase 2a (ASCEND GO-1) in TED	Y IMMUNOVANT
Apr. 2020	HL161 (HBM9161), initiation of Phase 1b/2a in NMOSD in China	HARBOUR
Jul. 2020	HL161 (HBM9161), initiation of Phase 2 in MG in China	HARBOUR BIOMED
Jul. 2020	HL161 (HBM9161), initiation of seamless Phase 2/3 in ITP in China	HARBOUR
Aug. 2020	HL161 (IVMT-1401), topline data of Phase 2a (ASCEND MG) in MG	Y IMMUNOVANT
4Q 2020	HL036, HanAll to present clinical results from VELOS-2 in DED at AAO 2020	₩ 대용제약
4Q 2020	HL036 (HBM9036), initiation of Phase 3 in dry eye disease in China	HARBOUR
4Q 2020	HL161 (IVMT-1401), Immunovant to announce 3 additional indications	Y IMMUNOVANT
1Q 2021	HL161 (IVMT-1401), initial data of Phase 2 (ASCEND WAIHA) in WAIHA	Y IMMUNOVANT
1H 2021	HL186/HL187, final lead candidate selection	₩ 대용제약
1H 2021	HL161 (IVMT-1401), initiation of Phase 3 study in MG	Y IMMUNOVANT
1H 2021	HL161 (IVMT-1401), topline results of Phase 2b (ASCEND-GO2) in TED (AKA GO)	Y IMMUNOVANT
1H 2021	HL161 (HBM9161), topline results of Phase 1b/2a in NMOSD in China	HARBOUR BIOMED
2H 2021	HL036, initiation of Phase 3-2 (VELOS-3) in dry eye disease	M 대응제약

Revenue from milestone payments is steadily growing







Received & Expected milestone payments

2019

- A 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
- HL036 (Dry eye disease) in Q4 2020 expected

2021 (Expected)

- ♦ Harbour BioMed
 - HL161 (Autoimmune diseases) in 2021
- Roivant (Immunovant)
- HL161 (Autoimmune diseases) in H1 2021

Note: HanAll recognize an upfront and milestone payments from Immunovant for approximately 5.8 years until commercialization HANALL BIOPHARMA Co., Ltd. All rights reserved.

HanAll Highlights



Promising pipeline

- •HL161: front runner in the FcRn antibody class for broad autoimmune diseases
- •HL036: promising in dry eye disease and other indications

Accumulated R&D expertise

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

Successful partnerships

- Partnerships with Daewoong, Immunovant, and Harbour BioMed
- Expanding network through increasing global presence

Profitable existing business

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



Appendix

- √ Financials
- ✓ Sales breakdown

Financial Statements (Consolidated)



Income statement (condensed)

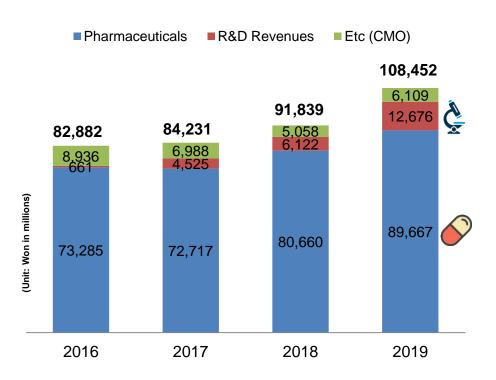
	(Unit: KRW Millio				
	2017	2018	2019	1H 2020	
Sales	84,231	91,839	108,452	44,698	
COGS	41,552	42,814	45,672	18,475	
Gross profit	42,679	49,026	62,780	26,223	
SG&A expenses	29,349	33,007	35,637	17,172	
R&D expenses	9,790	10,545	10,051	4,592	
Operating income	3,540	5,474	17,092	4,459	
Income before taxes	2,627	3,996	17,454	9,582	
Net income	5,813	3,300	20,007	9,774	

Balance sheet (condensed)

	(Unit: KRW N			
	2017	2018	2019	1H 2020
Current assets	138,372	128,409	134,569	129,040
Cash and cash equivalents	41,922	22,682	6,120	9,442
Short-term financial instruments	52,166	66,673	89,313	81,837
Financial assets at fair value through profit or loss	1,508	-	-	-
Trade and other receivables	19,110	17,522	22,630	17,929
Inventories	16,452	15,520	13,717	17,166
Other current assets	7,214	6,010	2,789	2,666
Non-current assets	30,323	33,896	64,891	68,511
Property, plant and equipment	13,379	13,769	14,373	14,758
Intangible assets	10,161	5,525	10,718	13,982
Other non-current assets	6,783	14,602	39,800	39,771
Assets	168,696	162,304	199,460	197,551
Current liabilities	52,788	21,805	26,453	21,216
Non-current liabilities	4,709	23,581	22,222	19,561
Total liabilities	57,498	45,386	48,675	40,777
Contributed capital	26,120	26,120	26,120	26,120
Capital Surplus and other components of equity	109,532	112,133	126,939	123,986
Retained earnings	(24,455)	(21,336)	(2,274)	6,668
Total equity	111,198	116,918	150,785	156,774

R&D Revenues and Pharmaceuticals Drove Sales Growth









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