

NOVEL BIOLOGICS FOR BETTER LIFE



Investor Relations | December 2021

창립일 13th of May, 2008

대표이사 박순재

본사 대전

IPO KOSDAQ: 196170 (2014년)

자회사 ▶ **Ceres F&D Inc. : 2018년 6월 설립**
(KGMP 공장/cGMP 준비)

- **Teicoplanin** (Glycopeptide 계열 항균제)
- **Tacrolimus** (면역억제제)
- **Everolimus** (면역억제제)



자회사 ▶ **Altos Biologics Inc : 2020년 11월 설립**

- Biosimilar 임상/사업화 (Eylea biosimilar 등)



▶ **LS메디텍**

- 의약품 도매업



ALTEOGEN's Business Domains

Platform Provider for Biobetter Drugs

- 독자적 기반기술을 바탕으로 제품 사업화 추진

Biobetter Platforms

2008 ~

Long-acting
Biobetter

2011 ~

Antibody-Drug
Conjugate (ADC)

Prioritized Biosimilars

2014 ~

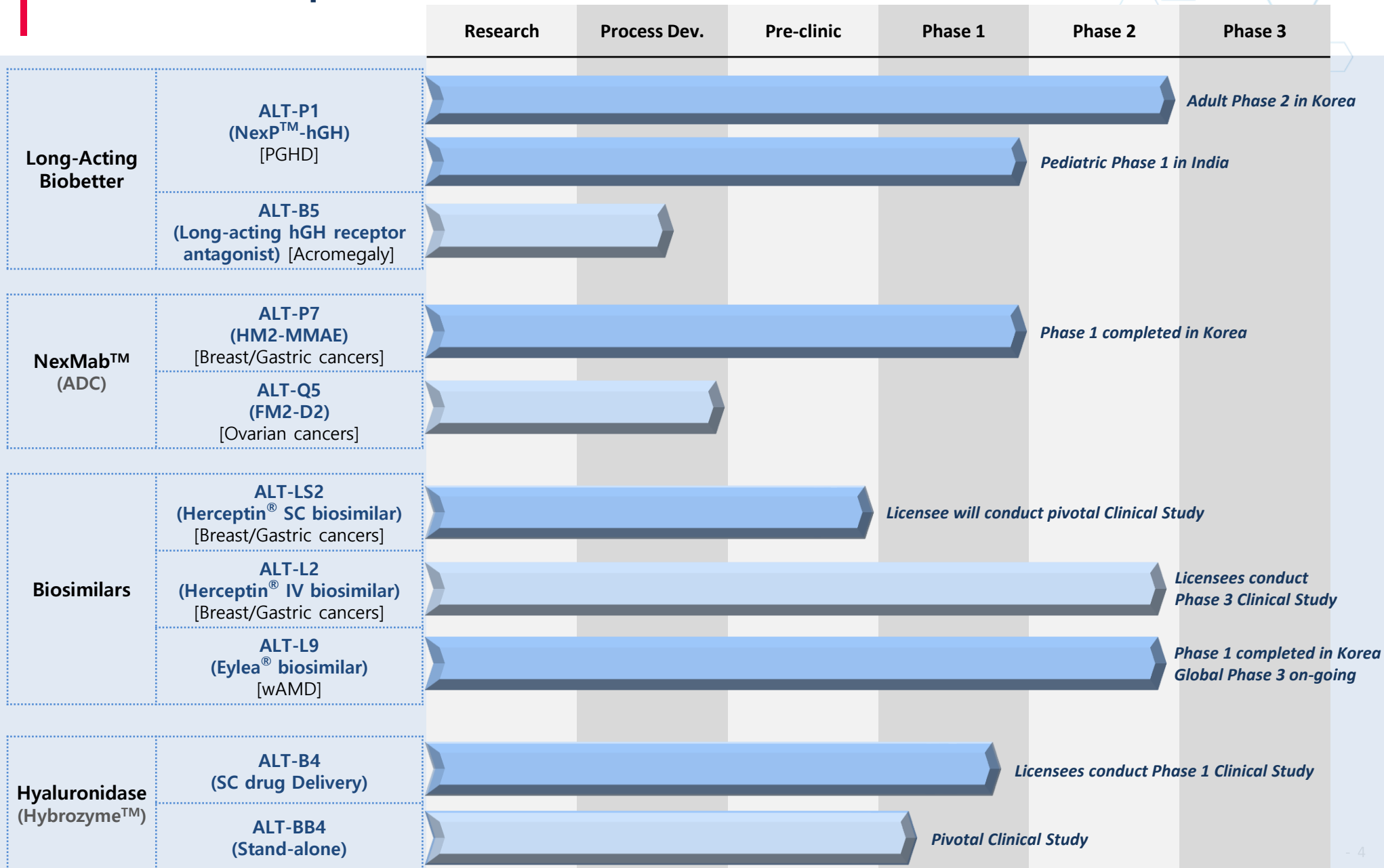
Biosimilars

Enabling Technology

2018 ~

Hyaluronidase

ALTEOGEN's Pipeline





Contents

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ALTEOGEN Inc.

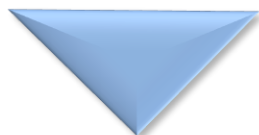
Novel Hyaluronidase

- **SC Drug delivery**
- **Tergase[®]** (Stand alone Hyaluronidase)
- **Diluase[®]** (IVF Usage)

ALT-B4 : Novel Hyaluronidase Hybrozyme™ Technology

Novel Human Hyaluronidase

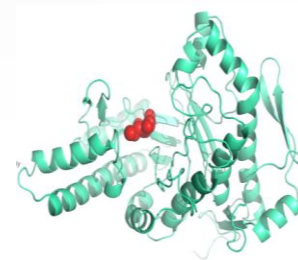
- ▶ Generation of PH20 variants by extensive computer modelling. Same mode of action(MoA) with PH20.
- ▶ Allows conversion of iv formulation of biologics to sc formulation



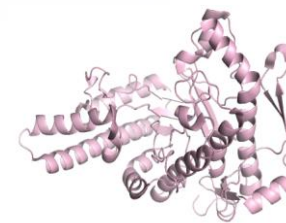
[Improved physicochemical & biological properties]

- Enhanced thermal stability and protein stability
- Higher Productivity
- Lower immunogenicity compared to wildtype PH20 determined by *in vitro* analysis

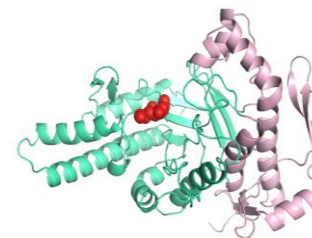
Hybrozyme™ Technology : Domain Swapping



PH20



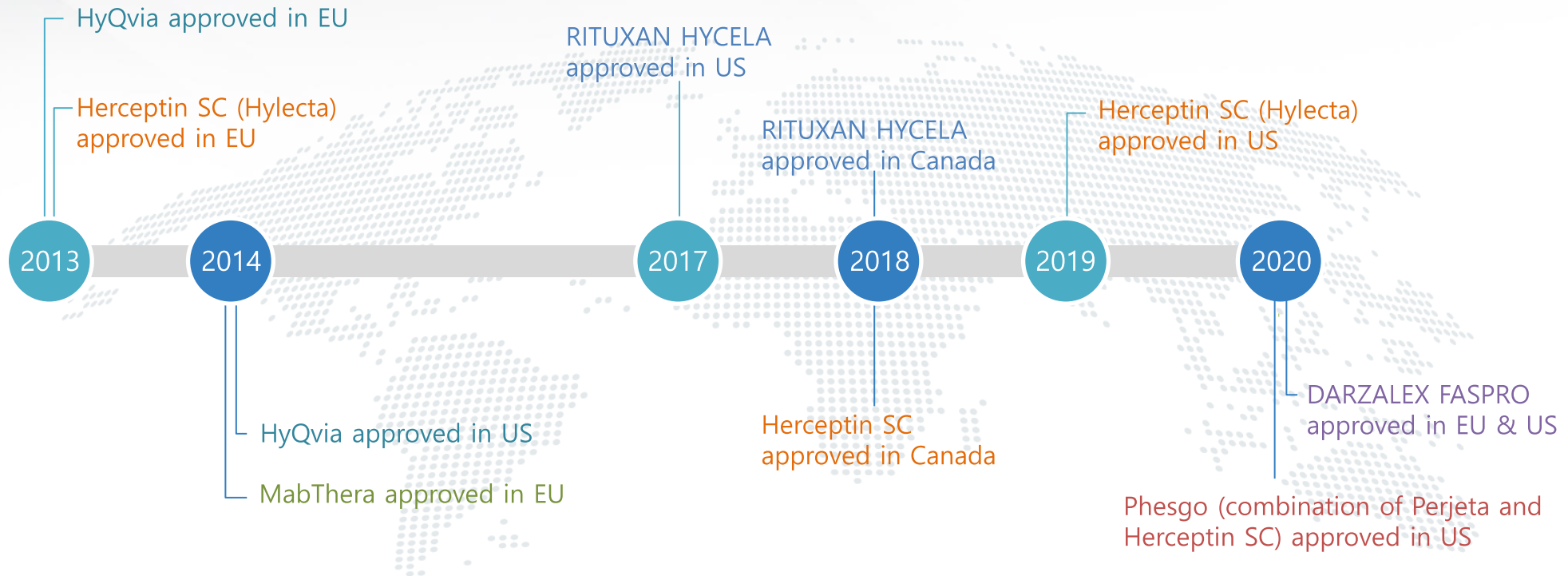
Hyal



ALT-B4

Commercialization of SC formulation with Hyaluronidase

- Five Mab products have been approved by FDA, EMA so far



- At present clinical trials of Mab sc products are actively conducted by global Pharma/Biotech companies
- > 500 Mab products are in clinical trial phase worldwide

ALT-B4 : SC Drug Delivery Business

■ Licensing-Out to global companies for SC formulations



Entered Non-exclusive License Agreement with a Top 10 Global Pharmaceutical Company **(Total US\$1.373B)**

- Clinical trial plan in 2022

Entered Non-exclusive License Agreement with a Top 10 Global Pharmaceutical Company **(Total US\$3.865B)**

- Initiation of Ph1 in 2021

Entered Exclusive License Agreement with Intas Pharmaceutical **(Total US\$109M + up to double-digit Royalty)**

- Pivotal clinical trial plan in 2022

In discussion with multiple global Pharmaceutical companies under MTA

(Flow of deal structure : CDA → MTA → Agreement)

*** Alteogen will provide ALT-B4 Drug Substance globally produced by EU CMO**

Multiple use of ALT-B4 for the same target bio drugs

- Based upon “Non-exclusive” licensing strategy, ALT-B4 has future potential for the more licensing opportunity in this important cancer target

	PD-1		PD-L1	
Collaboration with Halozyme	Nivolumab (Opdivo®)	BMS	Atezolizumab (Tecentriq®)	Roche
Marketed as IV	Pembrolizumab (Keytruda®)	MSD	Avelumab (Bavencio®)	Merck KGaA
	Cemiplimab (Libtayo®)	Regeneron	Durvalumab (Imfinzi®)	AstraZeneca
	Dostarlimab (Jemperli®)	GSK		
In clinical trials	Pimivalimab	Jounce therapeutics	Envafolimab	Alphamab
	Spartalizumab	Novartis	Cosibelimab	TG Therapeutics
	Camrelizumab	Jiangsu HengRui		
	Sintilimab	Eli Lilly	BMS-986189	BMS
	Tislelizumab	Beigene		
	Toripalimab	Coherus		
	Retifanlimab	Macrogenics		
	AMP-224, AMP-514	AstraZeneca		

Tergase[®] (Stand-alone Hyaluronidase)

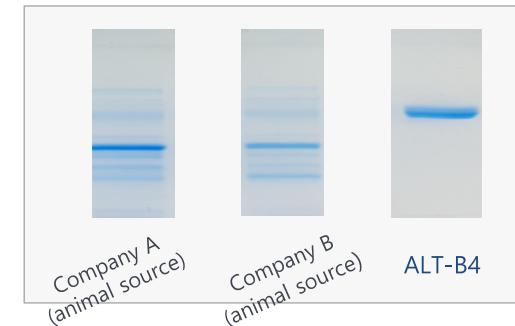
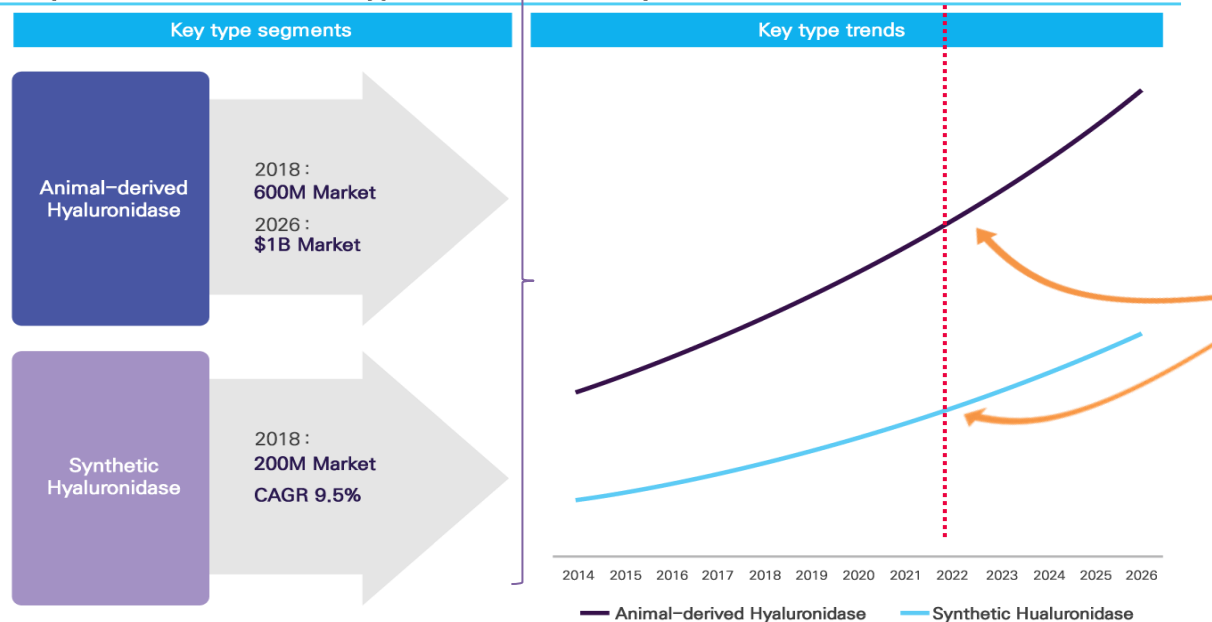
• ALT-BB4 : Approval of stand alone product for global market

- ✓ Replacing animal-derived Hyaluronidase
- ✓ Pivotal ph1 is on-going in Korea
- ✓ Starting with Korea launch in 1Q of 2023, it will be exported globally

Indications

• Dermatology • Ophthalmology • Plastic Surgery • Reduce Pain

Hyaluronidase market: Type movement analysis



✓ 2022 US\$1B Market

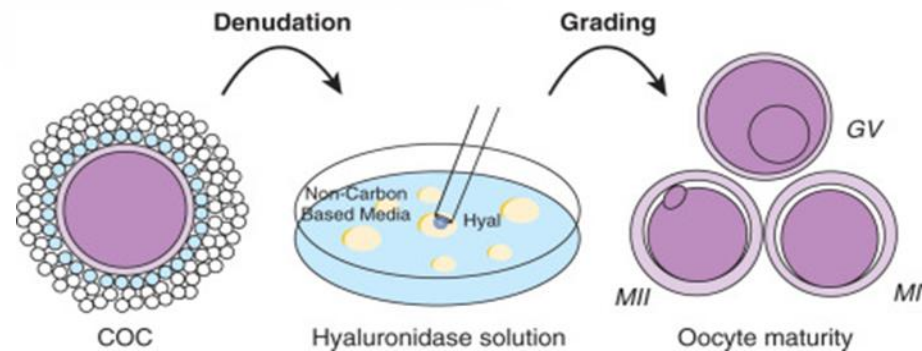
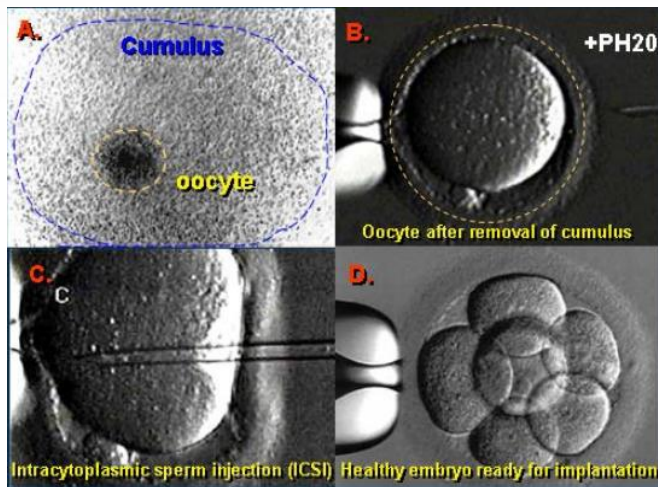


Source: WHO, U.S. CDC, FDA, NIH Journals, Investor Presentations, Primary Interviews, Grand View Research

Diluase[®] : IVF

• ALT-BC4 : Aid *in vitro* Fertilization

- 체외 수정 시 난모 세포를 둘러싼 적운 복합체(cumulus complex cell)와 코로나 방사를 제거하기 위한 용도로 사용



- Human recombinant hyaluronidase enhances fertilization & survival rates for intracytoplasmic sperm injection (ICSI)
- Studies have shown that **Diluase[®]** is effective and safe for use in Cumulus-Corona-Oocyte complex removal before ICSI
(*Journal of Animal Science & Technology* 4 월호에 게재, 논문제목: Toxicity of the recombinant human hyaluronidase ALT-BC4 on embryonic development)
- Global market size is near US\$ 1B

Alteogen has extensive patent ownership in ALT-B4 as well as PH20 production method

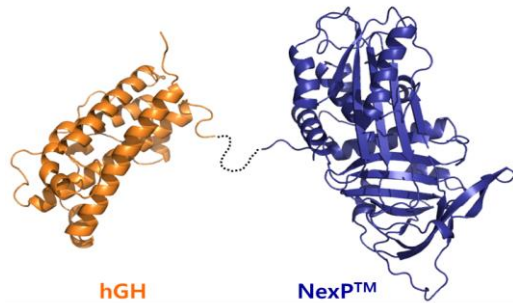
1. 신규 히알루론산 가수분해 효소 변이체 및 이를 포함하는 약제학적 조성물
 - 물질특허
 - 한국 등록/ 전 세계 12개국 출원 및 심사 중
2. 안정성이 향상된 신규 히알루론산 가수분해 효소 변이체 및 이를 포함하는 약제학적 조성물
 - 후속 물질특허
3. 인간 히알루로니다제 PH20 변이체와 약물을 포함하는 피하 투여용 약학 조성물
 - 항체 및 Drug 과 혼합한 조성 물 특허
 - 전 세계 100 개국에 특허 출원
4. 재조합 히알루로니다제의 생산 방법
 - ALT-B4, PH20 등 포유류 히알루로니다제의 생산 방법
5. 인간 히알루로니다제 PH20 변이체와 약물을 포함하는 피하 투여용 약학 조성물
 - 피하 투여용 제형 특허

Long-Acting Biobetter

- NexP™ fusion technology; long-acting hGH
- Long-acting hGH receptor antagonist

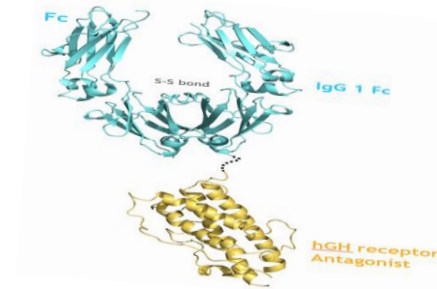
Long-acting Biobetter Products : hGH & hGH Antagonist

ALT-P1 (long-acting hGH)



- Weekly injection of hGH for PGHD
- Use of Proprietary NexP™ fusion carrier
- Finished Ph1b/ 면역원성 없음
- Global Ph2 will be initiated in 2022
- Global market : US\$ 4B
- Partner : Cristalia (Brazil)
- Orphan drug by USFDA

ALT-B5 (long-acting hGH Antagonist)



- Weekly injection of HGH antagonist for Acromegaly
- Use of Proprietary monomeric Fc technology
- Animal Proof of concept identified
- Superior to Pegvisoment® (twice per day injections)
- Global market : ~ US\$ 1-2 B
- 국가 신약개발 과제 선정 (2021)

Biosimilars

- Eylea® biosimilar development
- SC Biosimilar development

ALT-L9 : Eylea® Biosimilar

Ingredient

Aflibercept

Developer

Regeneron, Bayer

Indications

- Wet Age-related Macular Degeneration (wAMD)
- Diabetic Macular Edema (DME)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Myopic CNV

Patents
Expiration

- Substance Patent: 2024~2025
- Formulation Patent: 2027~2030

Molecule
Structure

Fc fused VEGF Receptors



► 2019 : US\$ 8B

► 2025 : > US\$ 10B Expected

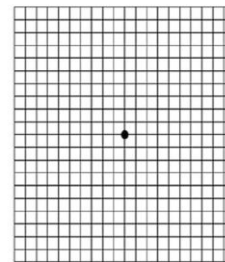
Drusen (deposits) causing macula degeneration (dry AMD)

8.7% of World population [WHO]

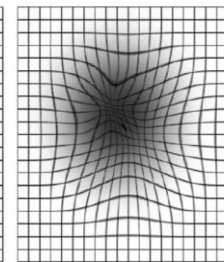
Abnormal new blood vessels cause rapid and severe loss of central vision (wet AMD)

~10-15% develop wAMD

Progression to reduced vision and blindness



Normal Vision



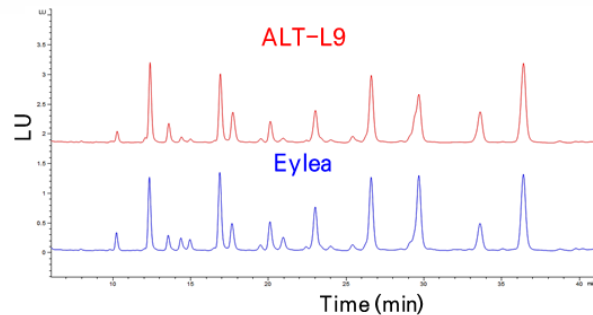
wAMD Vision

Leading cause of blindness in patients over 60 years old

ALT-L9 : Competitive Edge

01 Alteogen uses the same Cell Line which has been used by originator

- ✓ Cell line may affect the carbohydrate pattern and similarity in biosimilar products
- ✓ ALT-L9 has an excellent similarity in Glycan Profile comparing to Eylea®



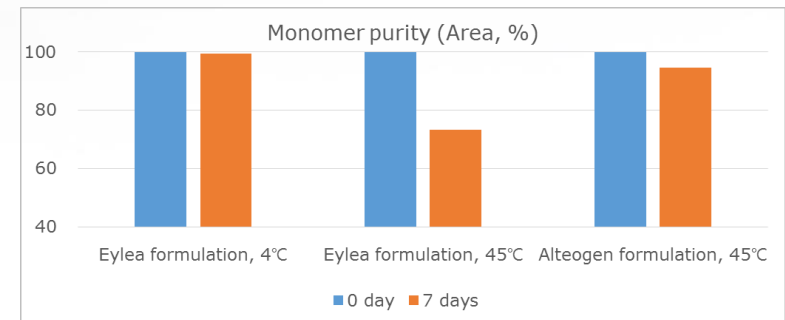
03 Alteogen obtained Process Patent

► Fermentation of fusion protein

- Other Eylea® biosimilar developing companies who produce Aflibercept under fed-batch fermentation mode may infringe Alteogen's fermentation patent.
- ✓ **Alteogen may block other companies' attempt to develop Eylea® biosimilar**
- ✓ **Registered in Korea, Japan, Russia, and Australia**

02 Alteogen developed a unique formulation

► Improved thermal stability

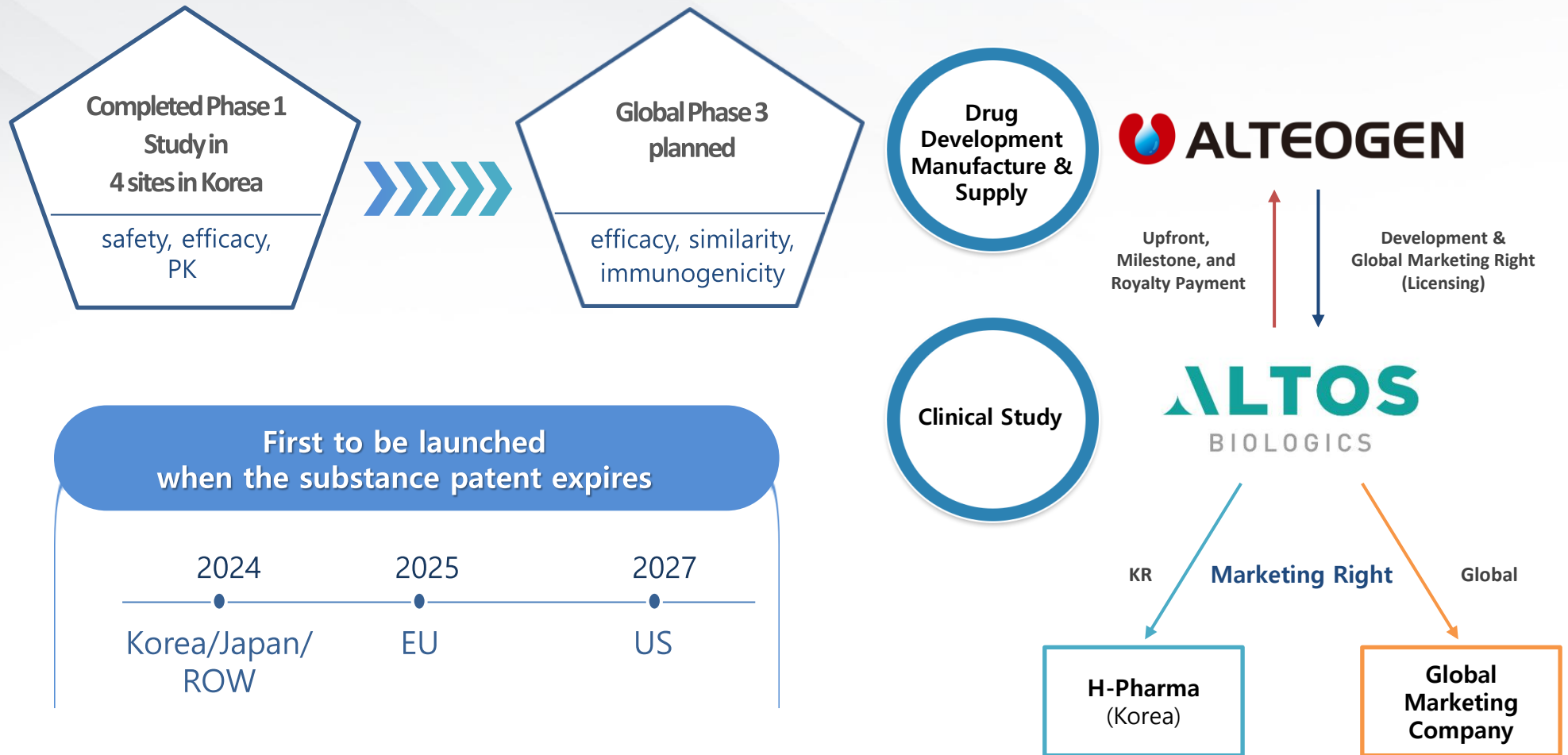


- ✓ The formulation patent of the originator expires in 2027-2030
- ✓ Patent is registered in Korea, US, Russia, and Japan and filed in 8 additional countries including EU

04 Alteogen filed PFS Formulation Patent

- ✓ Filed a patent for plastic pre-filled syringe (PFS) formulation and thermal sterilization in April 2021
- ✓ PFS is economic as a small amount can be filled in compared to vial type. The loss to be minimized as process of transferring drug from vial to syringe will not be necessary.
- ✓ This patent will strengthen ALT-L9's competitiveness

ALT-L9 : Business Model



**After launching in 2025 (Total Market US\$10B Expected),
Market Share Target : >20% in Eylea biosimilar Market**

DP Packaging trend : PFS

- “Eylea” 및 “Lucentis” 제품들은 최초 출시는 “Vial 제형”, “PFS 제형”으로 추가 승인
- PFS 제형으로 변경 배경 : 바이오 시밀러 경쟁력 강화
 - 1) 주사용 약물로 준비 시간 단축 및 오염 발생률 감소
 - 2) 시술의 편의성
 - 3) PFS 특허 출원
- ✓ Vial 제형과 동시에 PFS 제형으로 품목 허가 목표 ➡ 유럽 CMO 생산 계약



2019년 8월, 미국 FDA 추가 승인

- ✓ >80% market share in USA
- ✓ Only PFS will be marketed by originator

Development of differentiated biosimilar using ALT-B4

- Alteogen can develop **Blockbuster sc Biosimilar** using ALT-B4
⇒ establish differentiated biosimilar strategy



Herceptin® sc Biosimilar (US\$ 6.0 B)



Rituxan® sc Biosimilar (US\$ 7.0 B)



Opdivo® sc Biosimilar (US\$ 7.9 B)



Phesgo® sc Biosimilar (US\$ 4.3 B)



Remicade® sc New drug (US\$ 4.5 B)



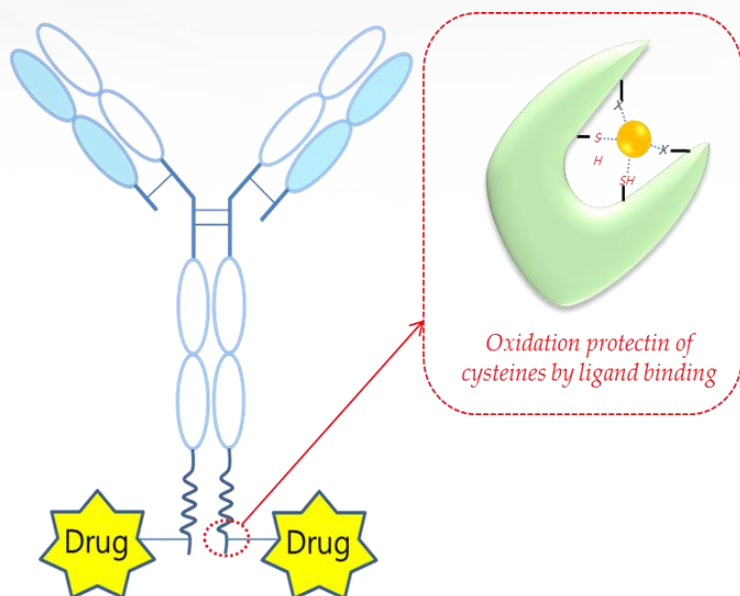
Darzalex® sc Biosimilar (US\$ > 6 B)

Antibody-Drug Conjugate

- Proprietary **NexMab™** conjugation technology
- anti-breast/gastric cancer ADC
- anti-ovarian cancer ADC

NexMab™ : Proprietary site-selective ADC conjugation technology

Alteogen's NexMab™ technology



Site-specific conjugation to
C-terminus of Fc

High productivity and homogeneity

Simple conjugation process

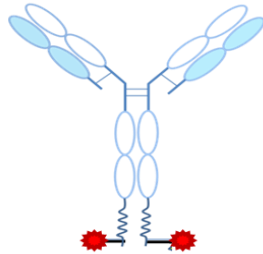
High in vivo stability and low toxicity

***Simple and efficient
site-specific conjugation technology***

Patent
Registered

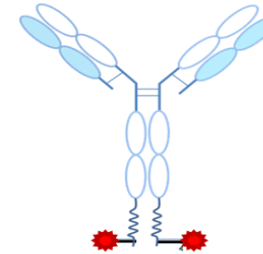
- USA (2017)
- EU (2020)
- Korea (2015)
- Russia (2016)
- Japan (2016)
- Mexico (2018)
- China (2018)
- Australia (2016)

ALT-P7 (Herceptin ADC)



- Her2+ Breast cancer
- Finished Ph1 to determine DLT
- 4.5 mpk MTD
- Target: 3rd line Her2+ breast cancer
- Plan: Combo clinical trial with IO
- Orphan drug designation for Stomach cancer

ALT-Q5 (Ovary cancer)



- Target: Folate Receptor
- Very high medical unmet need in Ovarian cancer
- Animal Proof of concept identified
- Global market : > US\$ 4-5 B
- No ADC available for Ovary cancer

| ALTEOGEN in 2022



◆ ALT-B4

- ✓ Preparation of Ph3 by a global partner
- ✓ Additional licensing agreements in sc use
- ✓ Application of MA **Tergase®**
- ✓ Marketing of **Diluase®**

◆ ALT-P1 & ALT-B5

- ✓ ALT-P1: Initiation of global Ph2 (by Cristalia)
- ✓ ALT-B5: Preparation of Pre-clinical trials

◆ ALT-L9

- ✓ Initiation of Global Ph3
- ✓ Collaboration with a global marketing partners, licensing to a global company

◆ ALT-L2

- ✓ Initiation of Ph3 in China (by Qilu)

◆ ALT-P7

- ✓ Preparation of combo study with IO



Thank you
for your attention!



www.alteogen.com