NOVEL BIOLOGICS FOR BETTER LIFE

ALTEOGEN

Company Introduction | November 2024

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ALTEOGEN Inc.

Company Overview

ALTEOGEN Inc.

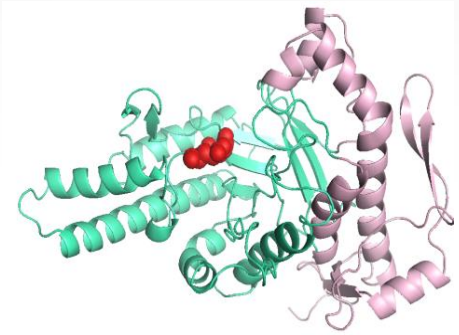
COMPANY OVERVIEW

Established	May 13th, 2008
CEO	Dr. Soon Jae Park, PhD
Headquarter	Daejeon, South Korea
IPO	KOSDAQ 196170 (2014)
Subsidiary	▶ Altos Biologics Inc. - Eylea® Biosimilar - Eylea® Biobetter ▶ Alteogen Healthcare - Tergase® Marketing - hGH

Timeline

- May 2008 Company founded
- December 2014 Listed on KOSDAQ
- November 2020 Altos Biologics established
- February 2024 Alteogen Healthcare established

ALTEOGEN Novel Biologics for Better Life : A Platform Provider



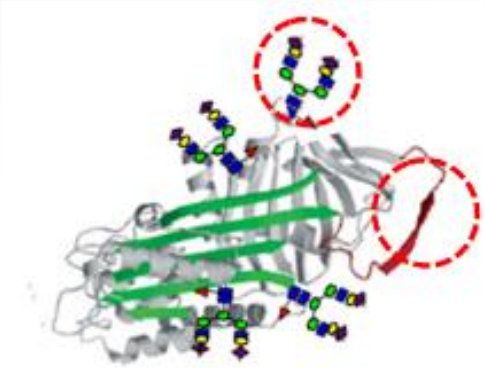
Hybrozyme™

Novel Human Hyaluronidase

Competitive Patent Portfolio
(Secured Substance, Co-formulation, Process patents)

L/O to Global Pharmas Including 2 Top 10 Pharmaceutical Companies

Exemption from IRA
Co-formulated product is not subject to Medicare Drug Price Negotiations



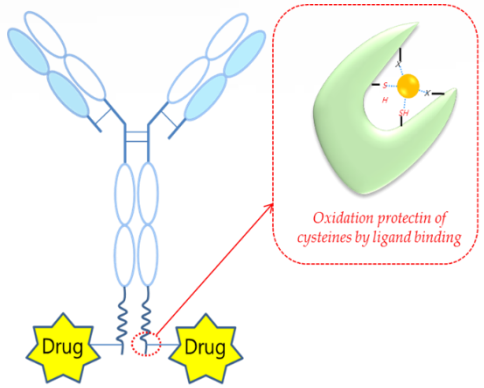
NexP™

Long-acting Biobetter

Biobetter Technology for Longer Dosing Cycles

Superior Performance Compared to Similar Long-acting Technologies

L/O to Cristália (Brazil): Weekly hGH



NexMab™

Antibody-Drug Conjugate

Site-Specific ADC Junction Technology

Core Technologies Applicable for Blockbuster ADC Products including SC ADC Products

ALTEOGEN From R&D venture to Global Bio Pharmaceutical Company

Approved

Tergase® (ALT-B4 STAND ALONE)
MFDS, Korea

ALT-L2 (Herceptin® BS)
NMPA, China by QiLu Pharmaceutical

Near Applications

Eylea® **Biosimilar** (ALT-L9)
MAA (EMA & MFDS)

Hybrozyme™ Platform
Application (ALT-B4)

Weekly hGH (**ALT-P1**)
Global Ph2 (DCGI)

Future Applications

ADC SC(subcutaneous)

Bispecific Antibodies ADC

NexP™ Platform
Orphan Drugs

Progress of Clinical Development

GPC / Multiple Bio companies → *Global Ph3, NDA*

ALTEOGEN Inc.

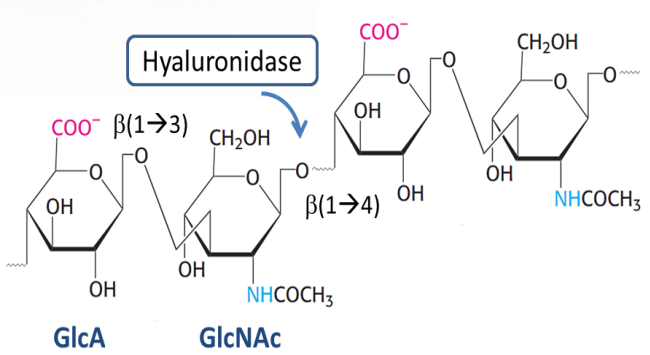
Novel Human Hyaluronidase

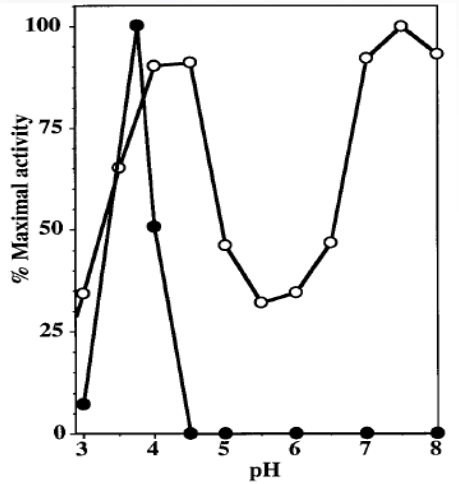
- Hybrozyme™ (Hyaluronidase Excipient)
- Tergase® (Hyaluronidase Human Injection)

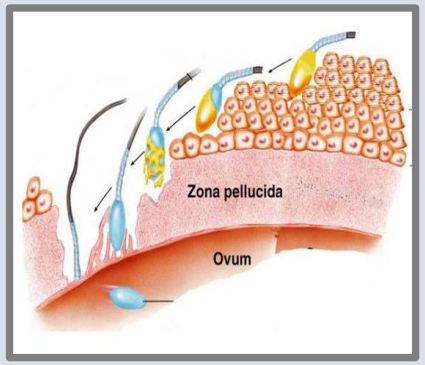
Hyaluronidase : Enzyme Hydrolyzing Hyaluronan in the Extracellular Matrix

Five Human Hyaluronidases

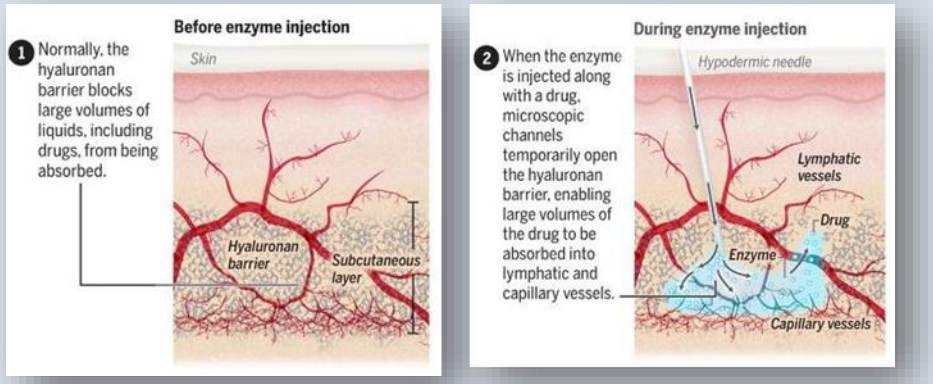
- Hyal1, Hyal2, Hyal3, and Hyal4: Optimum at pH 3
- PH20: Also active at pH 7~8







PH20 aids in penetrating the layer of cumulus cells



➢ Hyaluronidase enables IV infusion to SC injection when co-formulated with drugs

Hyaluronidase : Need for SC Formulation Enabling Platform

SC Formulation : High Demand for Patients – Pharmas – Healthcare Providers

Patients

- Increased patient convenience and quality of life
- Reduced preparation and administration time
- No IV infusion related side effects
- At-home self administration injections available

Healthcare Providers

- Increased efficiency in patient treatment
- Reduced patient observation time

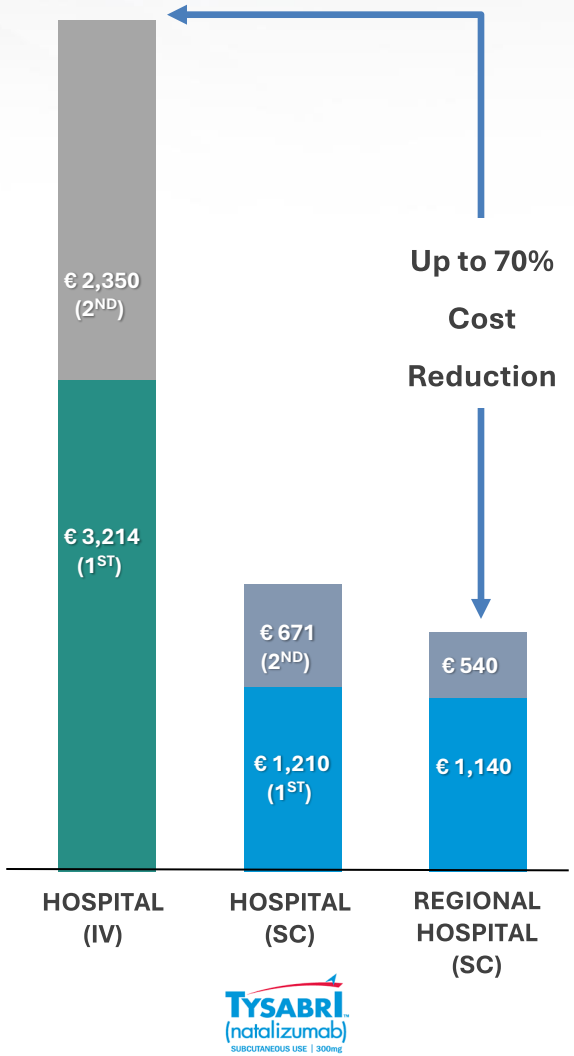
Global Pharmas

- Extended patent coverage through formulation change
- Exemption from IRA Medicare Drug Price Negotiations
- Competitive advantage against competing drugs
- Simple small scale PK/PD testing required

Hyaluronidase : Efficiency and Economic Advantages of SC Formulations

ex) TYSABRI®

Cost Comparison of Natalizumab IV / SC (2Yrs)



Economic benefits of SC administration
- Effective dosing management with SC vs IV
(IV .213h/2y >> SC. 84h/2y)

Avoiding drug prep, reducing admin process time, freeing up hospital capacity

Reduction in administration observation times

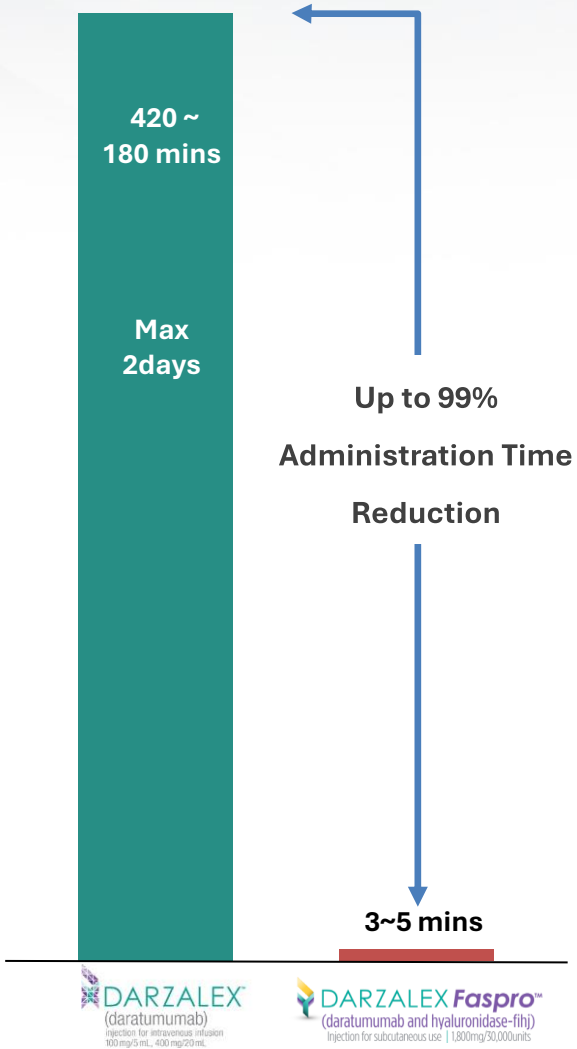
Free up healthcare professional staff while maintaining adequate control and patient adherence

- **Provides potential benefits to patients (Quality of Life) - Better Patient Compliance**
- **Reduces Healthcare Cost**
- **Superb benefits of SC injection over IV infusion**

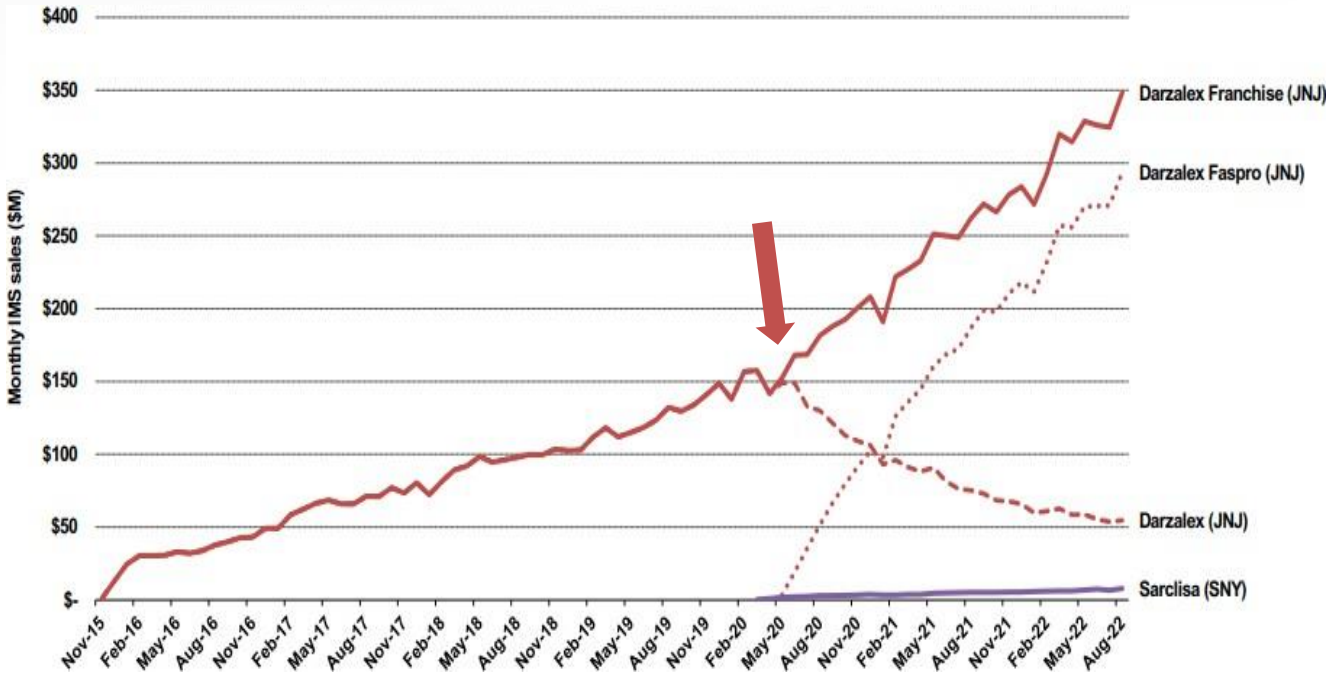
From: Torres et al, 2023

Hyaluronidase : Efficiency and Economic Advantages of SC Formulations

ex) DARZALEX Faspro®



Adopted from "Phil Green Consulting 2022"



- 84% of revenue from SC formulation after two years from the launch of DARZALEX Faspro®
- Excellent dosing convenience and low injection side effects / economically efficient
- Confirms rapid market adaptation of hyaluronidase enabled SC injection formulation

From: Morgan Stanley/IQVIA Monthly ($MM) Sales Trend

Hyaluronidase : SC Formulation Status

Approval Date	Product (Name/Target)	Developer	Note
2013	HyQvia®	Takeda	
	Herceptin® SC (Trastuzumab/HER2)	Roche	
2014	MabThera® SC (Rituximab/CD20)	Roche	
2020	PHESGO® (Trastuzumab + Pertuzumab/HER2)	Roche	**First Combination Drug in SC Formulation**
	DARZALEX Faspro® (Daratumumab/CD38)	J&J	
2023	VYVGART® SC (Efgartigimod/FcRn)	argenx	**First High-dose Autoimmune Disease Treatment in SC Formulation**
	TECENTRIQ® SC (Atezolizumab/PD-L1)	Roche	**First Immune Checkpoint Inhibitor in SC Formulation**
2024	OCREVUS® SC(Ocrelizumab/CD20)	Roche	

FDA/EMA

8 Products Approved
15+ in Development

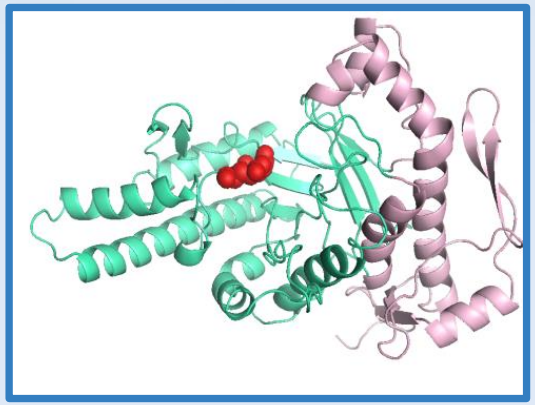
Follow-on L/O after Verification of Technology Platform

Anti-cancer Antibody Treatment
▶ Expansion to autoimmune diseases and other indications

SC Formulation Expected to be Applied to Combination Drug & Therapy

ALT-B4 : Novel Hyaluronidase from Hybrozyme™ Technology

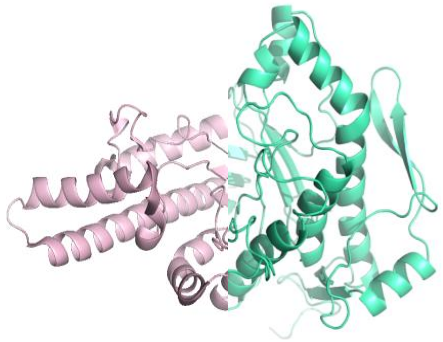
Novel Human Hyaluronidase : ALT-B4



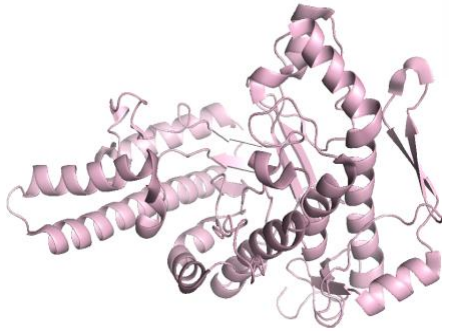
3D structure of ALT-B4 identified

[Improved properties compared to competitor's]

- **Enhanced protein stability with higher tolerance to thermal stress**
- **Higher specific activity**
- **Higher productivity**
- **Lower immunogenicity compared to wildtype PH20 confirmed in both *in silico* and *in vitro* analysis**
- **Extensive patent coverage**

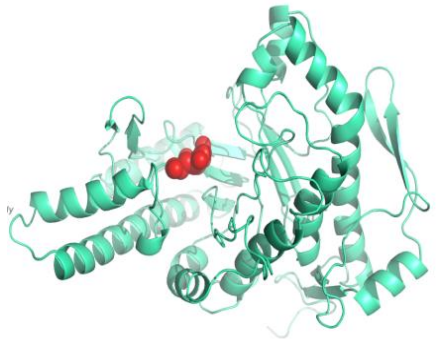


Generation of > 300 chimeric variants
Extensive activity assay and
other Physio-chemical assays



Hyal 1

3D structure of Hyal 1 identified



PH20

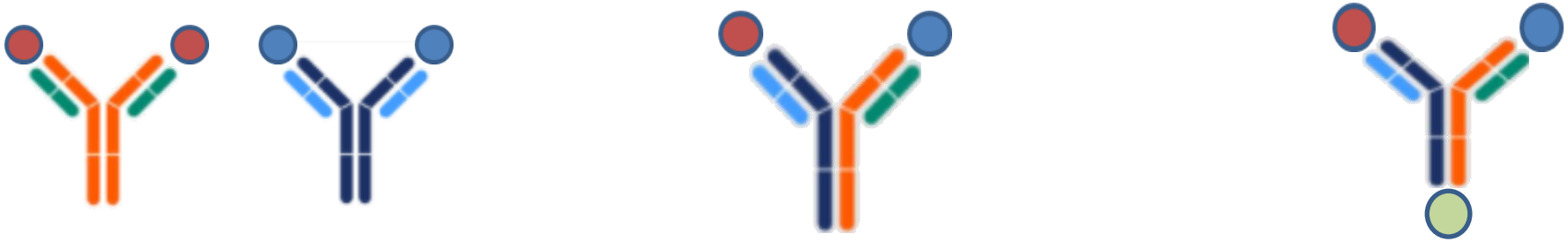
Simulation of PH20 based on Hyal1 structure
Computer modelling & identification
of domain substitution

ALT-B4 Licensing Strategy : Non-exclusive to the Target

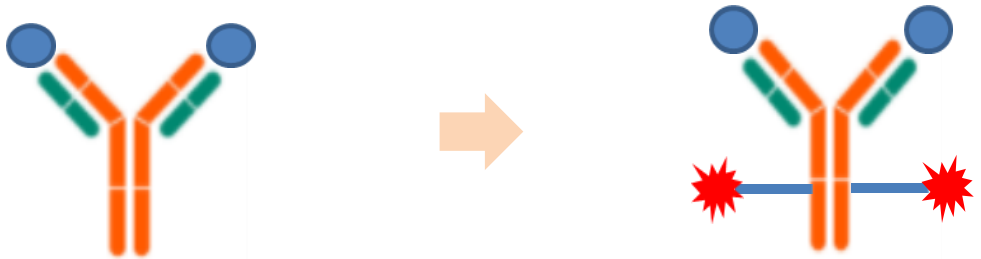
Multiple Collaboration Opportunities with Same-Target mAbs

Evolution of mAbs (Monoclonal Antibodies)

Single Target mAb → Bi specific mAb → Tri specific mAb



ADC (Antibody Drug Conjugate)



1st Gen mAb

Hybrozyme™ Licensing-Out Status

Licensing-Out SC Formulation Platform Technology for Multinational/Global Pharmas

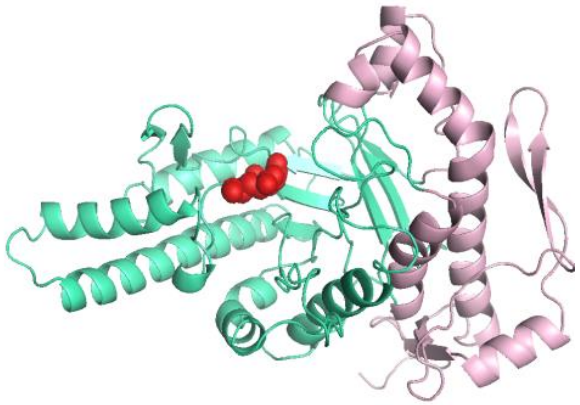
2019.12.02	Entered into a Non-exclusive License Agreement with **Top 10 Global Pharmaceutical Company**
2020.06.24	Entered into a Non-exclusive License Agreement with **MSD [shift to "exclusive" for Keytruda® on 2024.02.22]**
2021.01.07	Entered into an Exclusive License Agreement with **Intas Pharmaceuticals**
2022.12.29	Entered into an Exclusive License Agreement with **Sandoz AG [shift to "Joint Development" on 2024.07.30]**
2024.11.08	Entered into a Non-exclusive License Agreement with **Daiichi Sankyo [Enhertu® '1st ADC SC']**

In Discussions with Multiple Global Pharmaceutical Companies

Conversion from IV to SC : $$$ Potential Market

Alteogen has DS Supply Rights

Hybrozyme™ Platform Expansion



ALT-B4

Current Target for SC Formulation Development

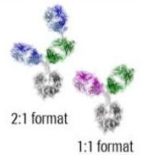
Future Development Target

Immunotherapy

mAb

Fusion Protein

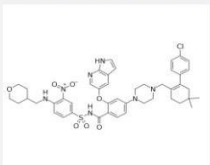
Bispecifics



Ex) Immune Checkpoint Inhibitors

Target Treatment

Small Molecules

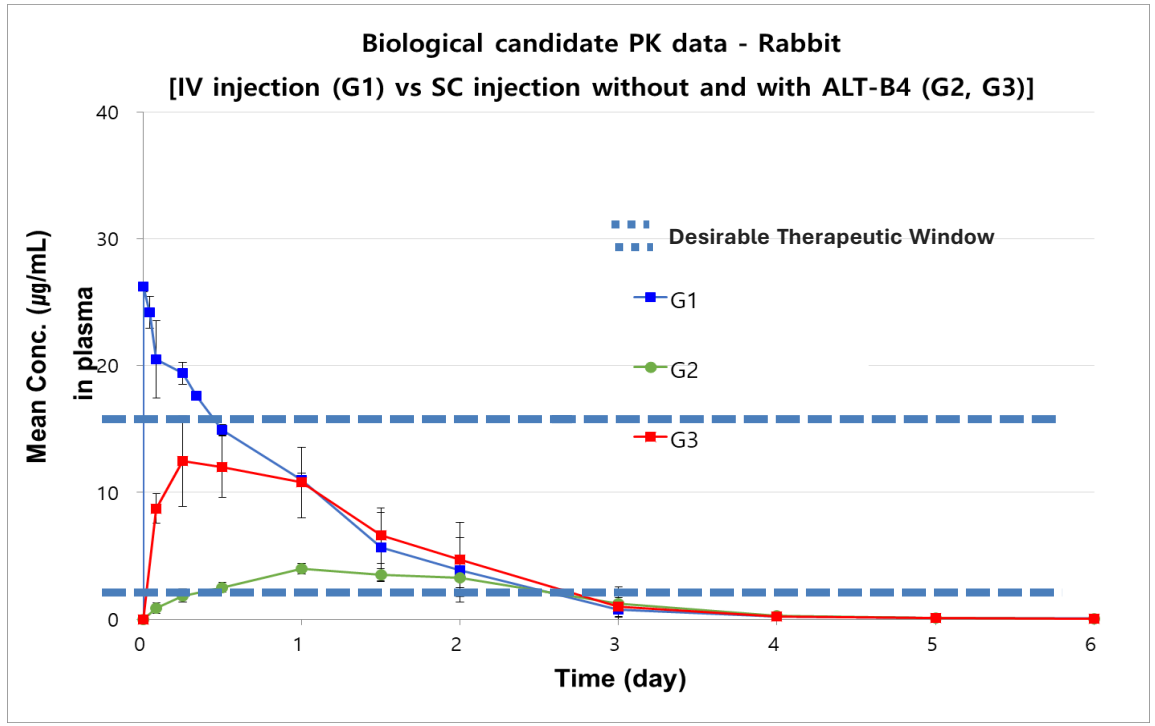


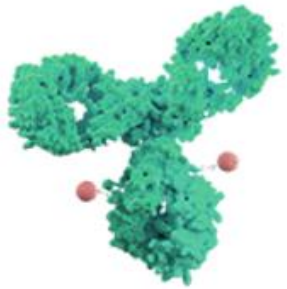
ADC

Images: from Roche Pharma Day, Sept 2022
Adopted from “Phil Green Consulting 2022"

Hybrozyme™ Platform Expansion (I)

Paradigm Shift in the ADC Field Expected





ADC SC Formulation

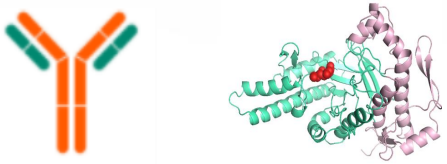
"Side effects, which is considered a critical hurdle in the ADC field, can be reduced while increasing patient convenience."

"Extension of exclusivity period for Blockbuster ADC products"

Hybrozyme™ Platform Expansion (II)

Life Cycle Management Platform

Life Cycle Management Platform Strategy



Drug A | ALT-B4

1. **A + 'ALT-B4'**

Even after expiration of A's patent, the patent period for the combination with ALT-B4 remains, maintaining **exclusive rights** to the SC formulation.

Patent extension by patenting a new formulation for the combination of A and ALT-B4

Extends Drug Exclusivity Period

Drugmakers go under the skin, skirting early US Medicare price negotiations

Michael Erman

July 28, 2023 · 4 min read

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CMS

CENTER FOR MEDICARE

DATE: June 30, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026

(중략)

If a drug is a fixed combination drug[34] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs. Therefore, all formulations of this distinct combination offered by the same NDA / BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. For example, a long-acting corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA / BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the long-acting corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

After 11 years (Regardless of Patent Expiration) post Launch of a Biopharmaceutical, Selection of IRA Medicare Drug Price Negotiation will be Implemented if Biosimilars are not Released

June 2023 CMS Guidelines "*If a drug is a fixed combination drug with two or more active moieties/active ingredients, the distinct combination of active moieties/active ingredients will be considered as one active moiety/active ingredient for the purpose of identifying qualifying single source drugs.*"

July 2023 Media Reports

MSD / J&J / Halozyme, etc. 'Subcutaneous drugs using hyaluronidase are expected to be recognized as new drugs'

Possibility of Exemption from IRA Medicare Drug Price Negotiations

10 drugs selected for the Medicare Drug Price Negotiation Program for the first cycle under IRA

The negotiated prices are 38% to 79% less than the 2023 list price

Drug Name	Participating Manufacturer	
Eliquis	Bristol Myers Squibb	2012
Jardiance	Boehringer Ingelheim	2014
Xarelto	Janssen Pharms	2011
Januvia	Merck Sharp Dohme	2006
Farxiga	AstraZeneca AB	2014
Entresto	Novartis Pharms Corp	2015
Enbrel	Immunex Corporation	1998
Imbruvica	Pharmacyclics LLC	2013
Stelara	Janssen Biotech, Inc.	2009
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc.	**Novolog: 2000** **Fiasp: 2017**

* Fiasp (insulin aspart) is a newer formulation of NovoLog with niacinmide (vitamin B3) added.

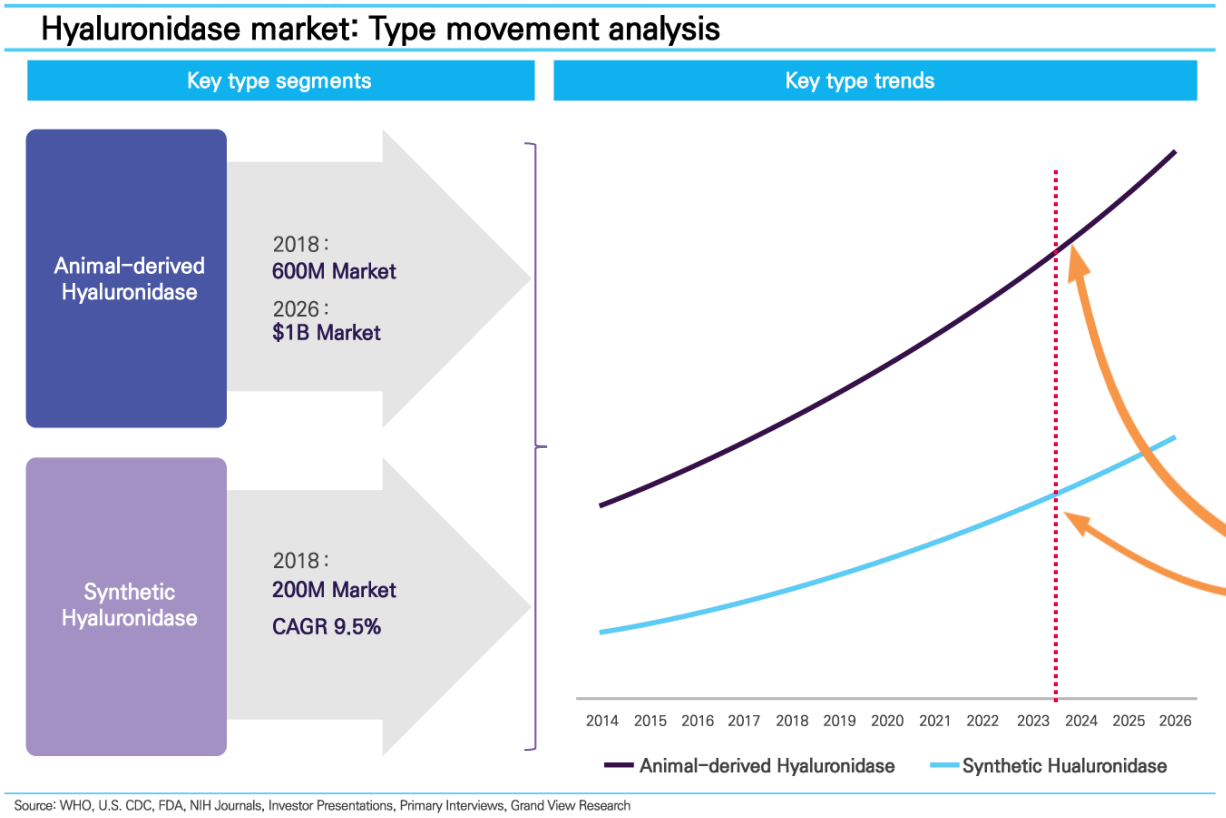
- **Negotiated prices for initial price are applicable in 2026**
- **Selection Criteria**
  - **Drugs for which at least 7 years, or biologics for which at least 11 years have elapsed between the FDA approval or licensure and the drug publication date**
  - **No generic of biosimilar completion**
  - **Highest total Medicare Part D gross covered prescription drug costs**
- **FDA Approval: Novolog (2000), Fiasp (2017) ⇒ Same API (insulin aspart)**

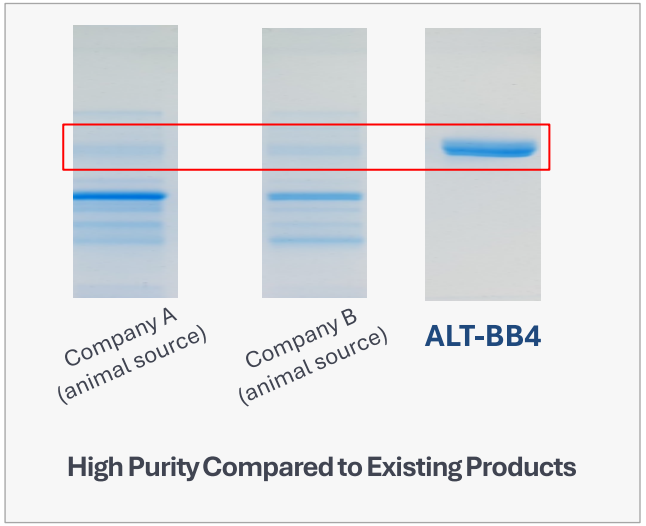
ALT-B4 is classified as an API by US FDA

Tergase® : Hyaluronidase for Human Injection

Indications • Dermatology • Ophthalmology • Plastic Surgery • Pain Management

- ✓ Substantially better alternative to animal-derived hyaluronidase
- ✓ Pivotal clinical trial completed in Korea, Market authorization in July 2024
- ✓ Korea launch in 2024 with subsequent global launch





- 2024 $1B Market

Tergase® : Hyaluronidase for Human Injection

Pivotal Clinical Trial

- **Completed Pivotal Clinical Trial with 244 Subjects at 4 Hospitals in Korea**
- **NDA Applied to MFDS Feb. 7 2023**
- **Market Authorization July 5 2024**

Clinical Trial Results

- **No ADA observed**
- **Superior Stability Compared to Competing Products:**

<Injection Site Reactions: Clinical Results>

Animal-derived Hyaluronidase>> PH20 (Halozyme) > Tergase ®

(Showed lower injection site reactions while clinically administering a 20 times higher dose than animal-derived hyaluronidase and a 4 times higher dose than PH20)

Tergase®

- **Standalone Hyaluronidase product administered subcutaneously to reduce pain or swelling after dermal filler injection or surgeries**
- **Recombinant human hyaluronidase of higher purity (99%) offers a safer option compared to animal-derived products that contain foreign protein and have known side effects**

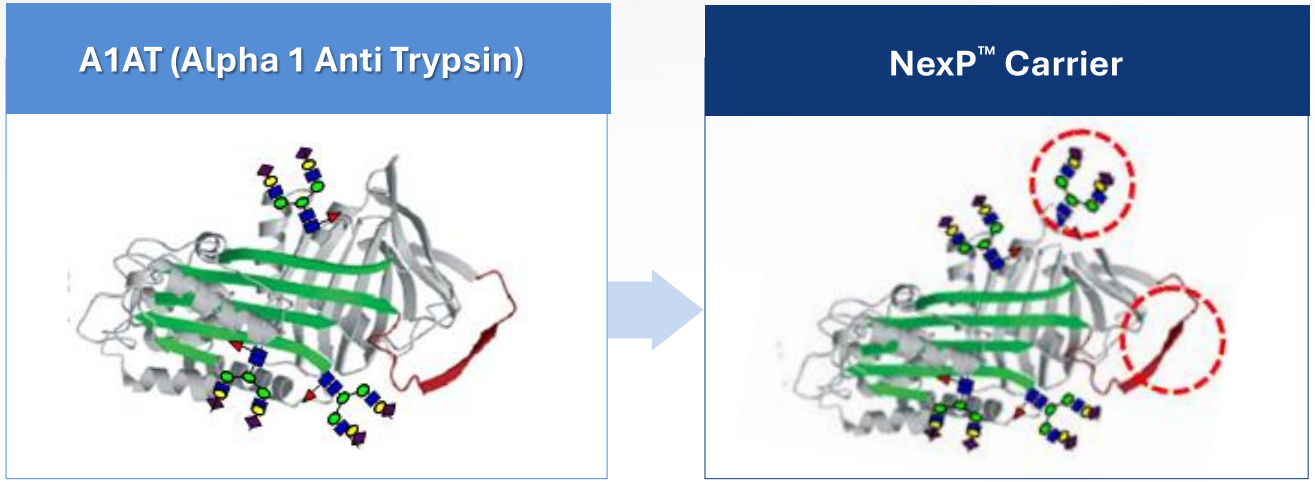
ALTEOGEN Inc.

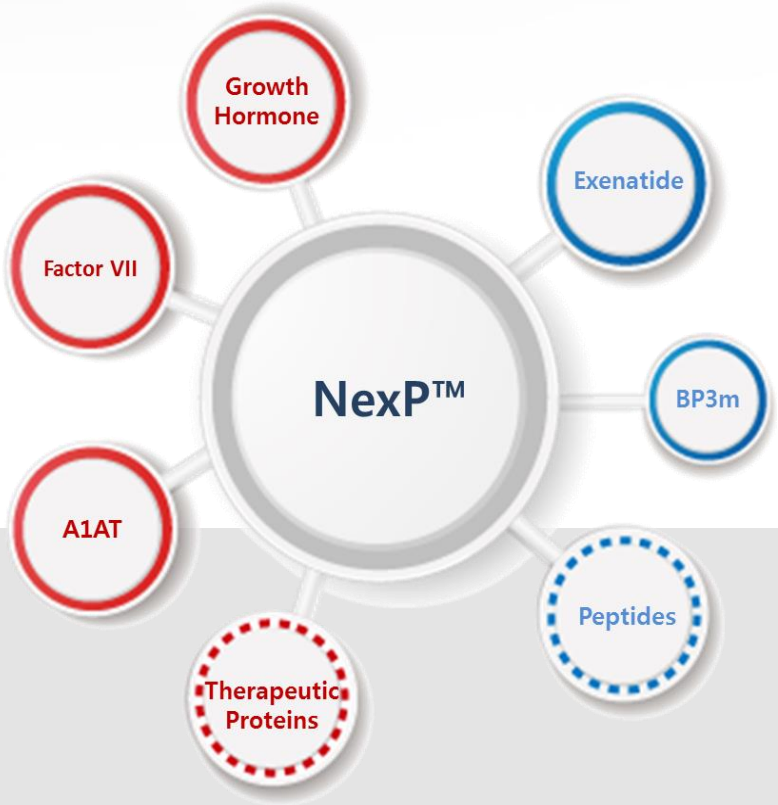
Long-acting Biobetter

- NexP™ Fusion Technology Overview
- ALT-P1 (Long-acting hGH)

NexP™ Fusion Technology : Long-acting Biobetter

Long-Acting Biobetter Platform NexP™





▸ Platform Introduction

- Long-acting technology developed by utilizing the abundant A1AT protein in human blood
- Safety confirmed by emphysema treatment etc.

▸ Key Functions

- Can be fused to the C, N-terminus of therapeutic protein; abundant expandability
- Maintains *in-vivo* activity of therapeutic proteins; extends half-life
- Based on abundant substances in the blood; low risk of immunogenic response

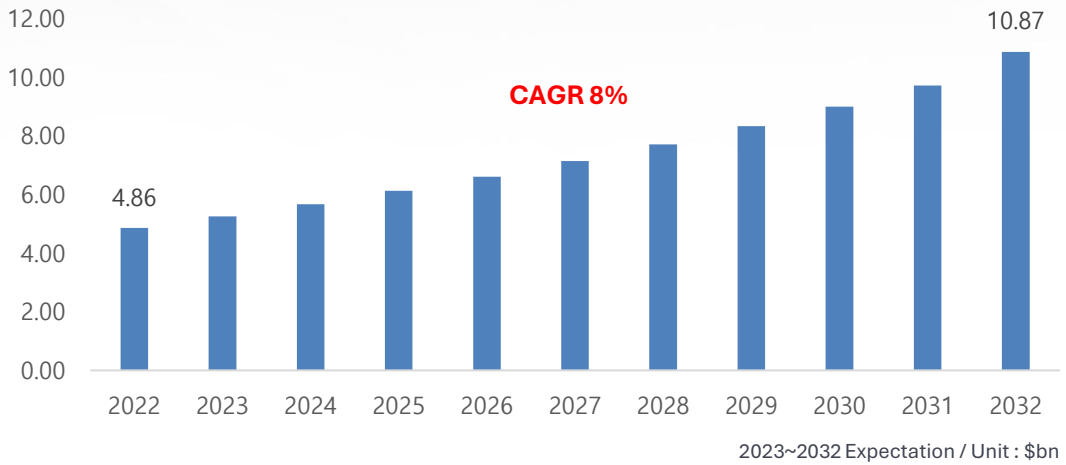
▸ Pipeline

- ALT-P1 long-acting human growth hormone; global phase 1b clinical trial completed for pediatric growth hormone deficiency, domestic phase 2 clinical trial completed for adults
- ALT-B5 persistent acromegaly treatment; under development in pre-clinical stage

ALT-P1: Long-acting Human Growth Hormone

Future Plan for ALT-P1

Growth Hormone Global Market



2023~2032 Expectation / Unit : $bn

- ✓ Increase sales by designating human growth hormones as medical insurance and reducing patient resistance
- ✓ Increasing demand for pediatric growth hormone deficiency (PGHD)
  - : 3 types of long-acting human growth hormones approved in US
  - : ALT-P1 designated as orphan drug by US FDA

SKYTROFA® (Ascendis, August 2021 FDA approval)
SOGROYA® (Novo Nordisk, April 2023 FDA approval)
NGENLA® (Pfizer, June 2023 FDA approval)

2019 Licensed-out to Cristália, Brazil

- ✓ Licensed-out to Cristália, Brazil
- ✓ Completion of Ph1b
- ✓ Aug 2024 Pediatric Ph2 IND Approved from DCGI
- ✓ Alteogen : Global market rights outside of Latin America
- ✓ Cristália : Latin America market rights
- ✓ Alteogen is capable of additional L/O from regions other than Latin America

Increasing Demand of Long-Acting Growth Hormone

*Precedence Research / EUGENE Investments and Securities(2023)

ALTEOGEN Inc.

Biosimilar

- ALT-L9 (Eylea® Biosimilar)
- ALT-L2 (Herceptin® Biosimilar)

ALT-L9 Eylea® Biosimilar

Active 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

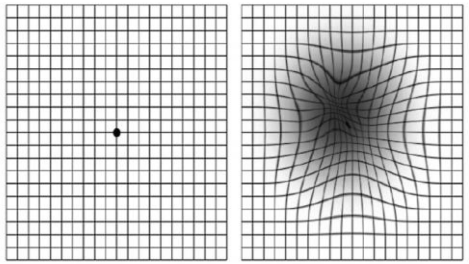
► **2022 : US$ 9.6B**

► **2027 : > US$ 15.3B 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

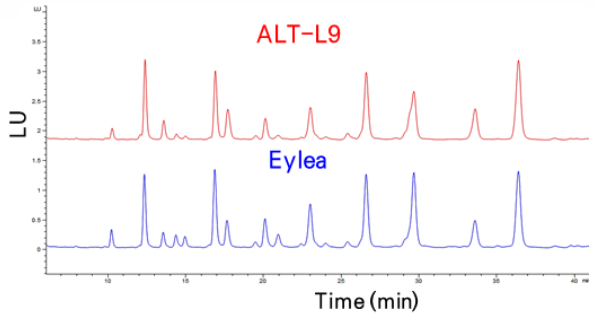
wAMD Vision

Leading cause of blindness in patients over 60 years old

ALT-L9 Competitive Edge

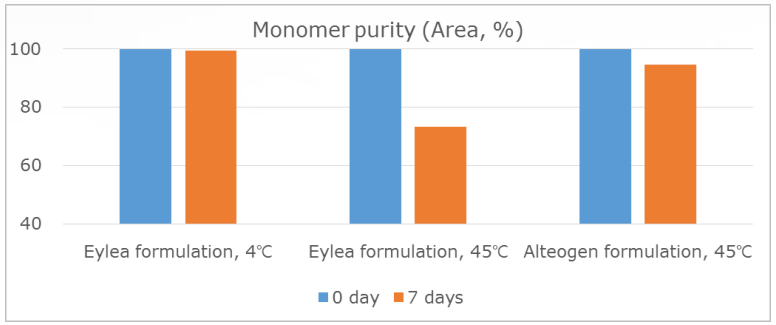
01 Same Cell Line Used by Originator

- ✓ Cell line may affect the carbohydrate pattern and similarity in biosimilar products
- ✓ ALT-L9 has an excellent similarity in glycan profile compared to Eylea®



02 Unique Formulation

- ► Improved thermal stability



- ✓ 36 month shelf life cf. 24 month by Eylea®

03 Process Patent

- ► Fermentation of fusion protein
- ✓ Process patent registered in Korea, Japan, Russia, and Australia. Patents filed in 7 additional countries.

04 Plastic Pre-filled Syringe

- ✓ Differentiator in highly competitive Eylea® biosimilar space.

ALT-L9 Phase III Clinical Study : Global Clinical Trial

Study Synopsis

Title	A multinational randomized, double-masked, active-controlled, parallel-group, Phase 3 Study to Compare the Efficacy, Safety, (Pharmacokinetics and Immunogenicity) Between ALT-L9 and Eylea® in patients with neovascular (wet) age-related macular degeneration
Investigational drug	Study drug: ALT-L9 (2.0 mg/eye), Comparator: Eylea®, EU (2.0 mg/eye)
Indication	Neovascular (wet) age-related macular degeneration
Design	Multicenter, randomized, double masked, active-controlled, parallel-group, Phase 3 study
Number of Countries	Total of 12 countries including EU, Korea and Japan
Number of Sites	112 sites
Number of Subjects	431 subjects

- ✓ Patient Enrollment Completed Feb. 2023 / Phase III Completion end of 2023
- ✓ MAA Submission to EMA / MFDS 2024
- ✓ Launch after Substance Patent Expiration in 2025 (EU)
- ✓ Pre-filled syringe (PFS) Launch after Vial Launch

ALT-L2 Herceptin® BS Development by QiLu Pharmaceutical

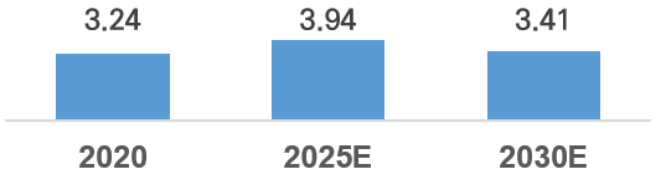
China Herceptin® Market

Herceptin® trastuzumab

- Early breast Cancer
- Metastatic Breast Cancer
- Metastatic Gastric Cancer

2019 Sales Share China / Global %	13.5%
2020 Sales Share China / Global %	20.0%
2020 Estimated Access Rate in Chnia	66.9%
2021 Potential Patient Number	112K

Market size (Million Unit) / 150mg



ALT-L2 Development Pathway

2016 Phase 1 Finished in Canada by Alteogen

2017 Licensed-out to QiLu Pharma (China)

- Total Payments : Undisclosed
(Industry Average Royalty)

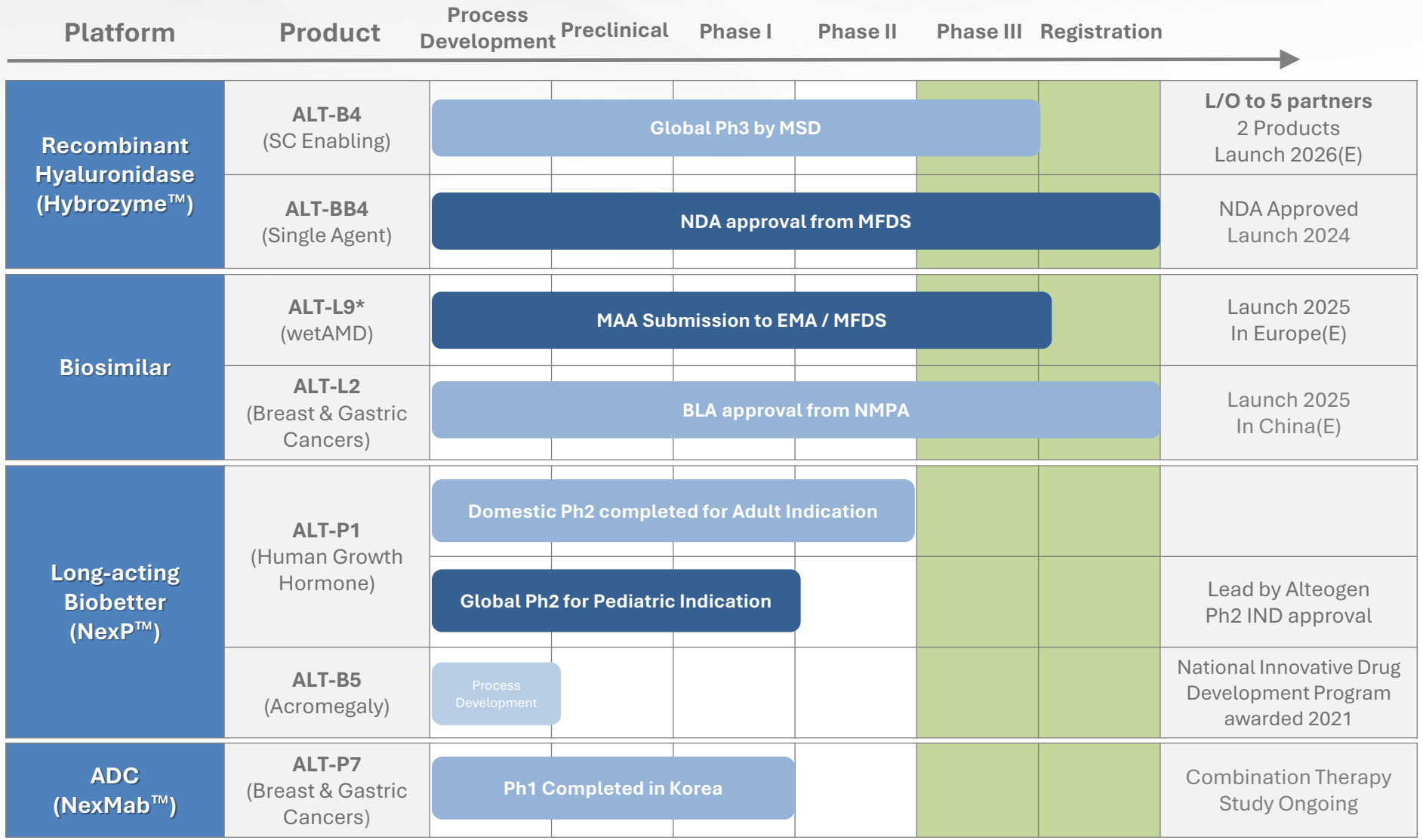
2022 Phase 3 Finished in China : 500 Subjects

2023 CDE BLA Application

2024 CSR to be Received + BLA Prep
Received BLA approval from NMPA

2025 1H Commercialization in China

Alteogen Pipeline



** Managed by Altos Biologics*

Preparation of Commercialization

Thank you for your attention!

ALTEOGEN

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