

NOVEL BIOLOGICS FOR BETTER LIFE



ALTEOGEN

Company Introduction | Oct. 2025

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ALTEOGEN Inc.

Company Overview

Established

May 13th, 2008

CEO

Soon-Jae Park, Ph.D.

Headquarters

Daejeon, South Korea

Stock code

KOSDAQ 196170

Subsidiary

▶ Alteogen Biologics

- Eylea® biosimilar
- Eylea® biobetter
- Tergase® sales & marketing
- hGH sales & marketing

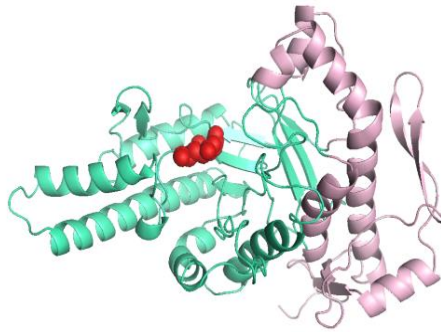
Website

www.alteogen.com

Journey of Innovation

- May 2008 Company founded
- Dec. 2014 IPO & listed on KOSDAQ
- July 2018 Hybrozyme™ platform development
- Dec. 2019 First Hybrozyme™ licensing deal with a Big Pharma company
- July 2024 Tergase® approved by MFDS (Ministry of Food and Drug Safety)
MAA submission to EMA for Eylea® biosimilar 'EYLUXVI®(ALT-L9)'
- May 2025 Alteogen Biologics established
- Sep. 2025 EYLUXVI®(ALT-L9) approved by the European Commission
Partner MSD received FDA approval for KEYTRUDA QLEX™

Alteogen's Core Technology Platforms



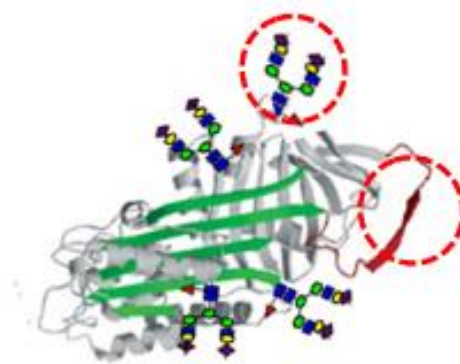
Hybrozyme™

Novel Human Hyaluronidase

Enabling large volume subcutaneous delivery

Competitive patent portfolio
(Secured substance, co-formulation, and process patents)

Licensed to global top pharmaceutical companies



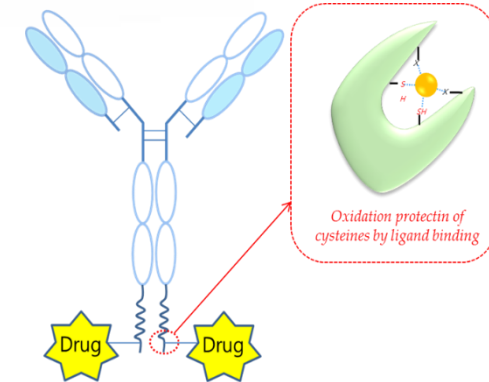
NexP™

Long-acting Biobetter

Biobetter technology for longer dosing cycles

Superior performance compared to similar long-acting technologies

Licensed to Cristália (Brazil): Weekly human growth hormone (hGH)



NexMab™

Antibody-Drug Conjugate

Site-specific ADC junction technology

Core technologies applicable for blockbuster ADC products including SC ADC products

Robust Pipeline

*The 1st product utilizing the Hybrozyme technology, **Keytruda Qlex™**, received FDA approval in September 2025*

Approved

Tergase (ALT-B4 stand alone)
MFDS, South Korea

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

EYLUXVI®(ALT-L9) Eylea® Biosimilar
EMA, Europe

Hybrozyme™ Platform (ALT-B4)
FDA, Keytruda SC by MSD

In Development

Hybrozyme™ Platform (ALT-B4)
Multiple products by partners, including Enhertu® SC by Daiichi Sankyo

Weekly hGH (ALT-P1)
Global Phase 2

New Technology

Once-monthly drug delivery platform

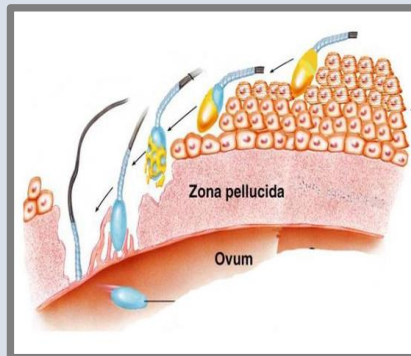
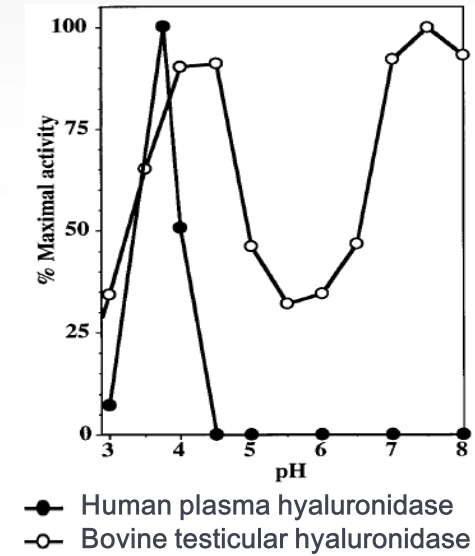
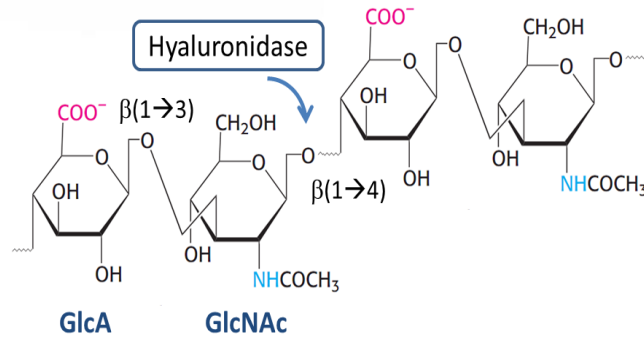
Novel Human Hyaluronidase

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

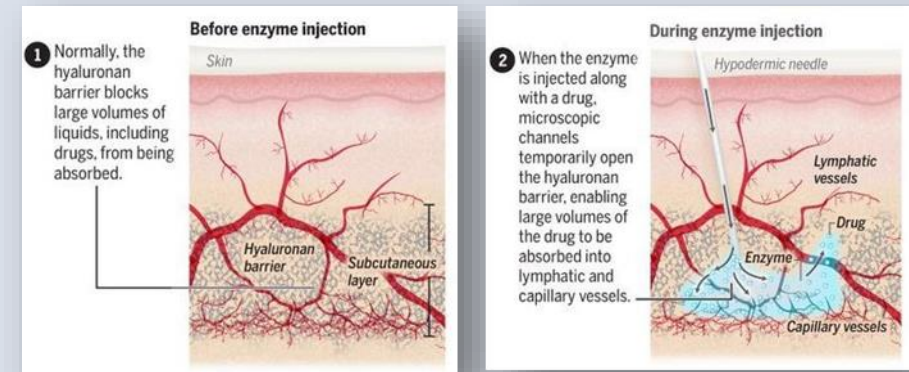
Hyaluronidase: An Enzyme that Hydrolyzes Hyaluronan in the Extracellular Matrix

Five Human Hyaluronidases

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



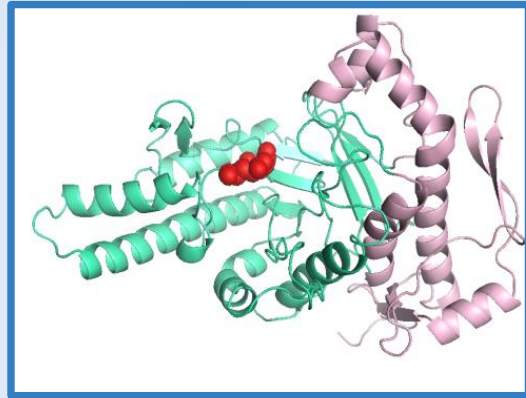
PH20 aids in penetrating the layer of cumulus cells



➤ Hyaluronidase enables large volume SC injections

ALT-B4: The Novel Hyaluronidase Advancing Subcutaneous Delivery via Hybrozyme™

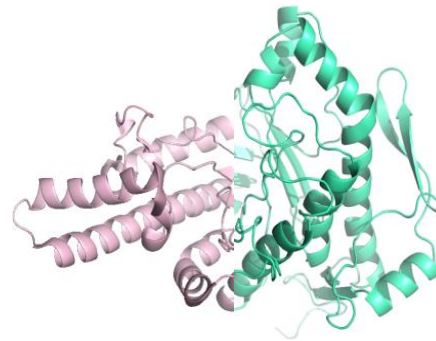
Novel Human Hyaluronidase : ALT-B4



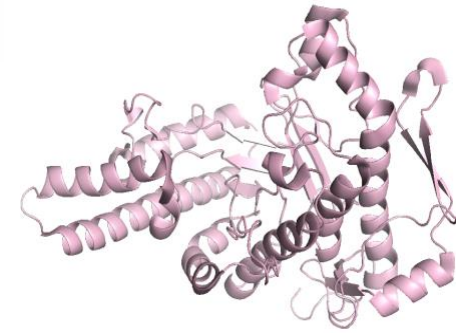
3D structure of ALT-B4 identified

[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 by *in silico*, *in vitro*, and *in vivo* analysis
- Extensive patent coverage (up to early 2043 in the US)

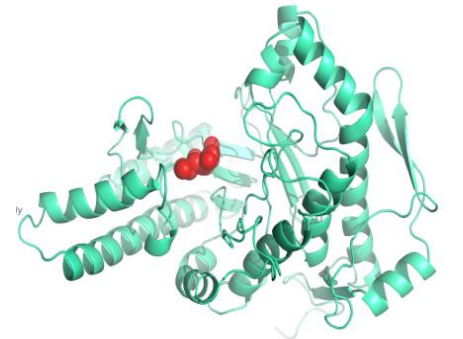


Generation of > 300 chimeric variants
Extensive activity assay and
other Physio-chemical assays



Hyal 1

3D structure of Hyal 1 identified



PH20

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

SC Conversion Catalyst: Why Hyaluronidase is Essential for Next-Gen Injectable Drugs

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

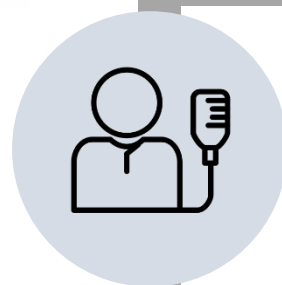
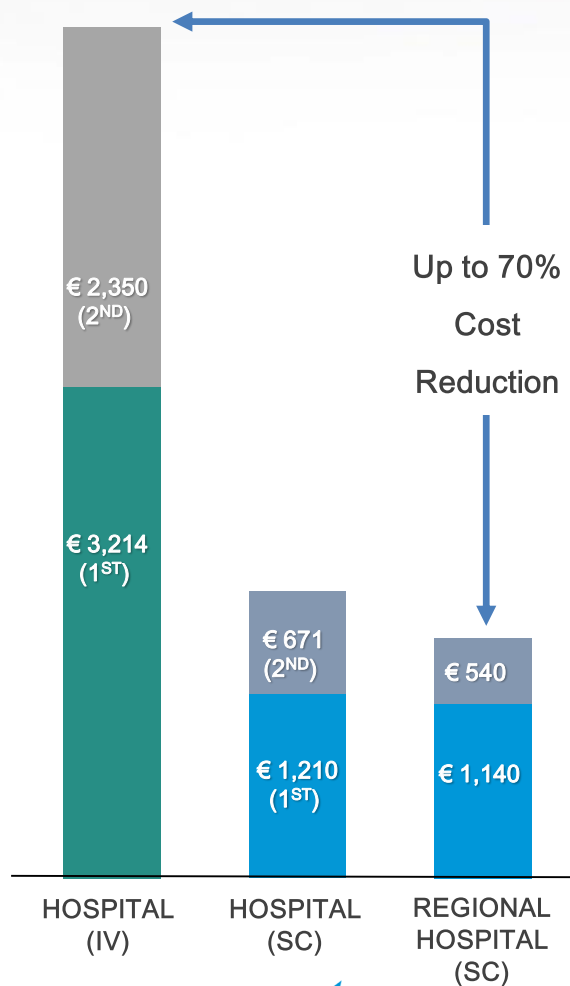


- Extended patent coverage through formulation change
- Exemption from IRA Medicare Drug Price Negotiations
- Competitive advantage against competing drugs
- Simple small scale PK/PD trials required

Efficiency and Economic Advantages of Subcutaneous (SC) Formulations

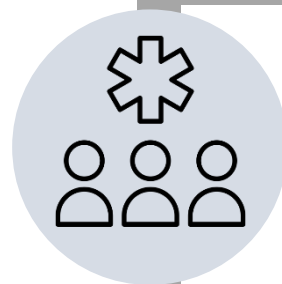
e.g. TYSABRI®

Cost Comparison of Natalizumab IV / SC (2Yrs)



Economic benefits of SC administration
- Effective dosing management with SC vs IV

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



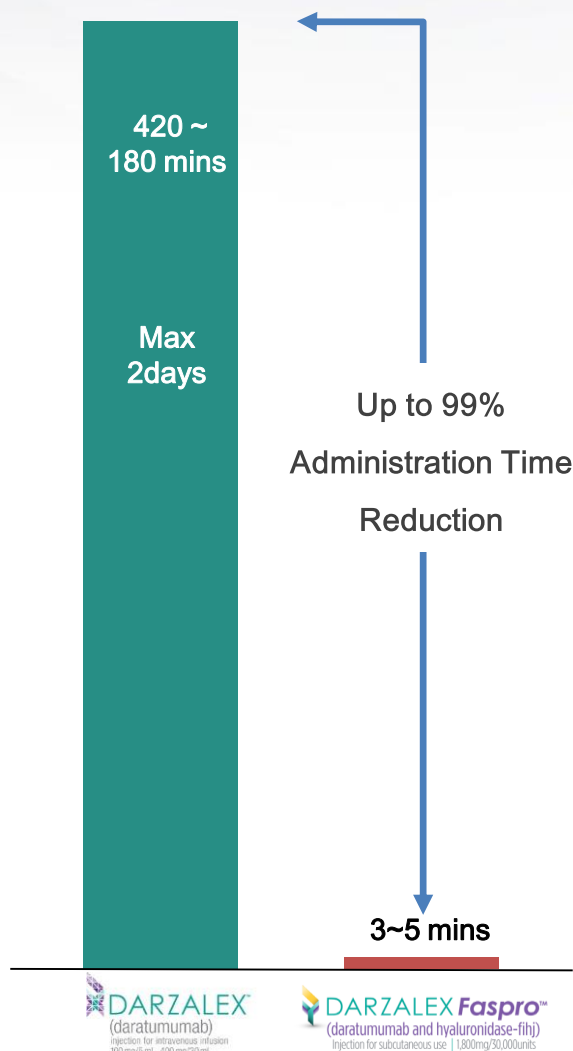
Reduction in administration observation times

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

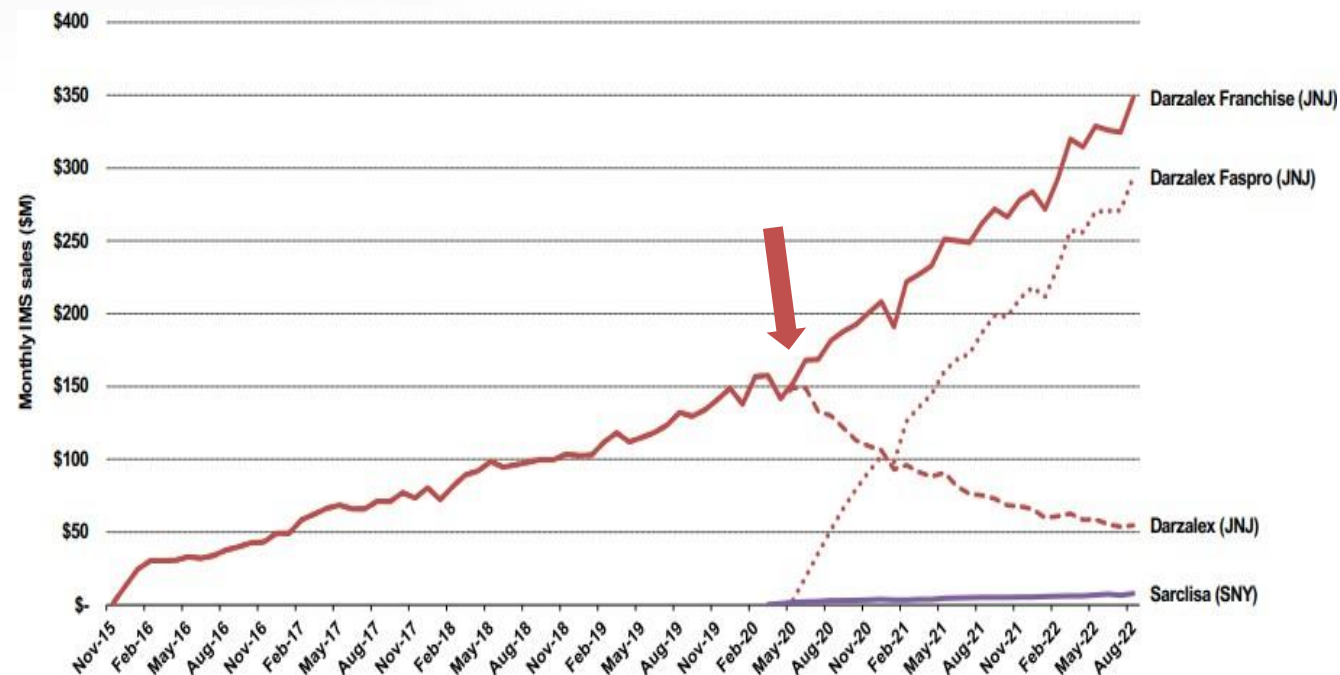
From: Torres et al, 2023

Efficiency and Economic Advantages of SC Formulations

e.g. DARZALEX Faspro®



Source: "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

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

Approved Subcutaneous (SC) Drug Formulations Co-Formulated with Hyaluronidase

Approval Date	Product (INN / Target)	Developer	Remarks
2013	HyQvia®	Takeda	
	Herceptin® SC (trastuzumab / HER2)	Roche	
2014	MabThera® SC (rituximab / CD20)	Roche	
2020	PHESGO® (trastuzumab + pertuzumab / HER2)	Roche	
	DARZALEX Faspro® (daratumumab / CD38)	J&J	
2023	VYVGART® SC (efgartigimod / FcRn)	argenx	
2024	TECENTRIQ Hybreza™ (atezolizumab / PD-L1)	Roche	
	OCREVUS® SC (ocrelizumab / CD20)	Roche	
	OPDIVO Qvantig™ (nivolumab / PD-1)	BMS	
2025	RYBREVANT® SC (amivantamab / EGFR&MET)	J&J	Approval in Europe
	KEYTRUDA QLEX™ (pembrolizumab / PD-1)	MSD	Approval in the US



FDA/EMA

10+ Products approved
15+ in development



Follow-on licensing deals
after verification of
technology platform



Anti-cancer antibody
treatments
► Expansion to
autoimmune diseases
and other indications



The SC formulation is
expected to be expanded
to include other modalities

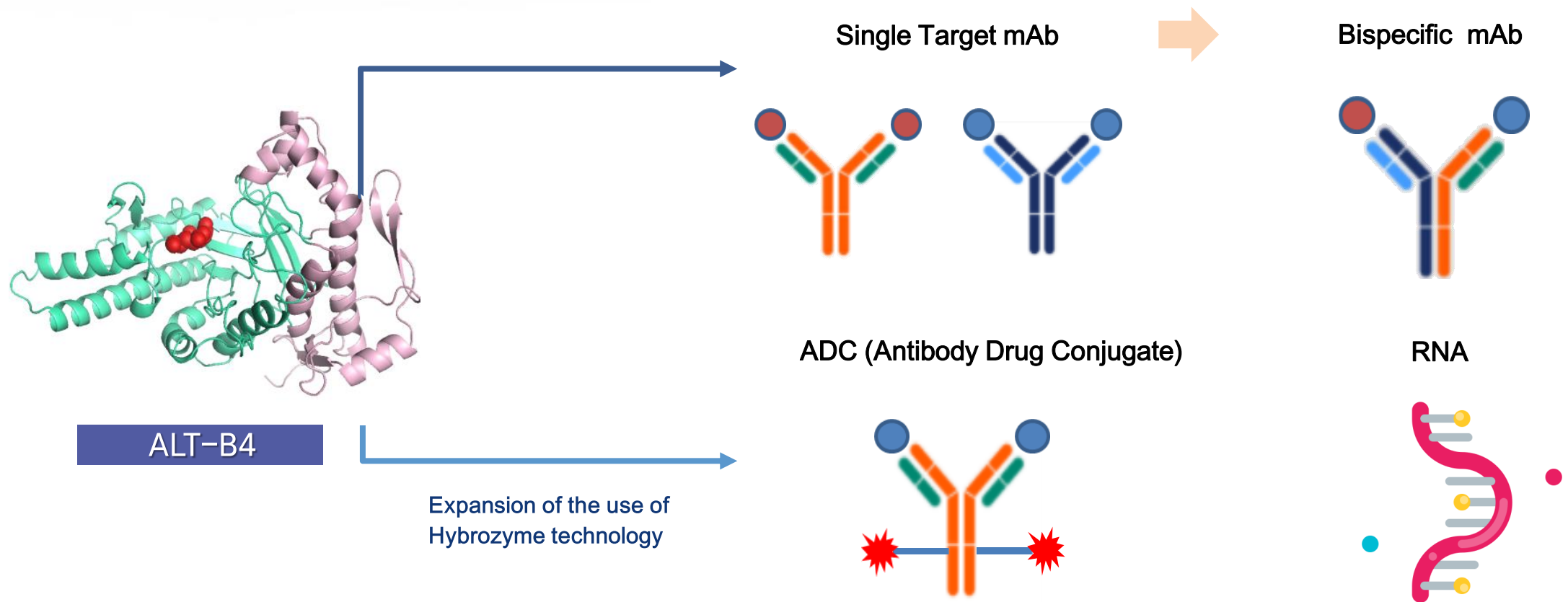
Keytruda SC: Superior Profiles Among Other PD-(L)1 SC Drugs

		 (pembrolizumab) Injection 100 mg		 nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL		 atezolizumab/hyaluronidase-tqjs SUBCUTANEOUS INJECTION 1875 mg/30,000 units	
Indication		Metastatic non–small cell lung cancer		Advanced/metastatic clear cell renal cell carcinoma		Locally advanced or metastatic non-small-cell lung cancer	
Dosage/Administration		SC	IV	SC	IV	SC	IV
		Pembrolizumab: 790 mg + Berahyaluronidase alfa 9,600 units	Pembrolizumab: 400 mg	Nivolumab: 1,200 mg + rHuPH20: 20,000 units	Nivolumab: 3 mg/kg	Atezolizumab: 1,875 mg (125 mg/ml) + rHuPH20: 30,000 units	Atezolizumab: 1,200 mg
		Q6W	Q6W	Q4W	Q2W	Q3W	Q3W
Administration time		About 2 min	About 30 min	About 3-5 min	About 30 min	About 7 min	About 40 min
Objective Response Rate (ORR)	Complete response (CR) + Partial response (PR)	45.4%	42.1%	24%	18%	12%	10%
DCR, %	Disease control rate (DCR)	84.5	88.1	62.5	62.8	-	
Median PFS, months	Progression free survival	8.1	7.8	6.34	5.65	2.8	2.9
Anti-hyaluronidase antibody	Non-treatment-emergent positive, n (%)	3.6%	-	N/A		11.4%	-
	Treatment-emergent positive, n (%)	1.5%	-			5.4%	-

Source: Public data

ALT-B4 Licensing Strategy : Non-Exclusive to Target

Multiple collaboration opportunities with same-target mAbs and different modalities



Hybrozyme™ License Agreements



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

2019.11.29	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 Sandoz [shift to “Joint Development” on 2024.07.30]
2024.11.08	Entered into an exclusive license agreement with Daiichi Sankyo [for Enhertu®]
2025.03.17	Entered into an exclusive license agreement with AstraZeneca
Current	In discussions with multiple global pharmaceutical companies

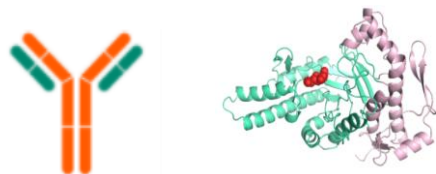
Conversion from IV to SC : \$\$\$ Potential Market
Alteogen retains global ALT-B4 drug substance supply rights

Potential IRA Advantages

Life Cycle Management Platform

Life Cycle Management Platform Strategy

Extends Drug Exclusivity Period



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

Possibility of Exemption from IRA Medicare Drug Price Negotiations



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

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



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 drug¹⁴ 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.”

Sep. 2025 CMS Final Guidance

- Fixed Combination Drugs: CMS is not making a change to the fixed combination drug policy in this final guidance. However, CMS describes its intent to address this program's integrity risk and that it is continuing to consider the appropriate policy to implement in rulemaking beginning initial price applicability year 2029.

Tergase®: Hyaluronidase for Human Injection

Pivotal Clinical Trial

- Completed a pivotal clinical trial with 244 subjects at 4 hospitals in South Korea
- NDA applied to MFDS Feb. 7, 2023
- Marketing Authorization July 5, 2024

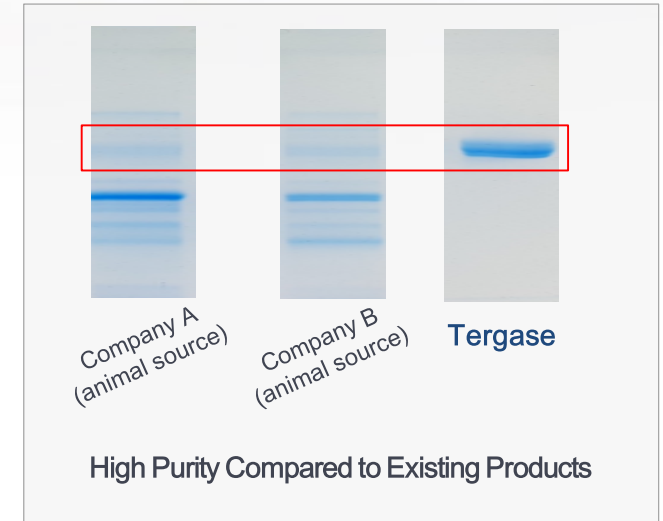
Clinical Trial Results

- No ADAs observed
- Superior stability compared to competing products:

<Injection Site Reactions: Clinical Results>

Animal-derived Hyaluronidase > Tergase®

(Showed lower injection site reactions compared to existing products)



Tergase®

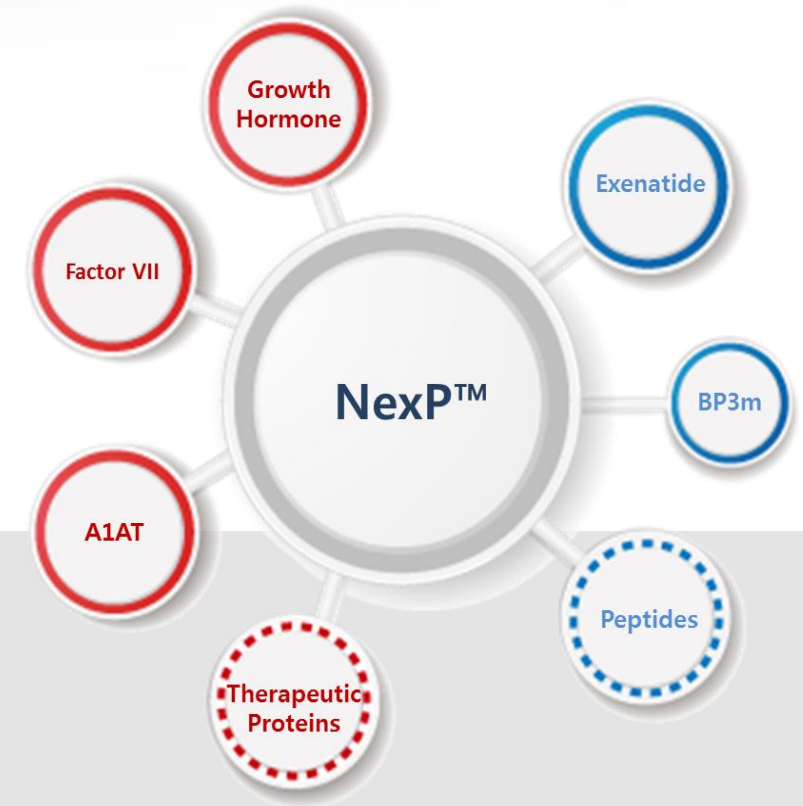
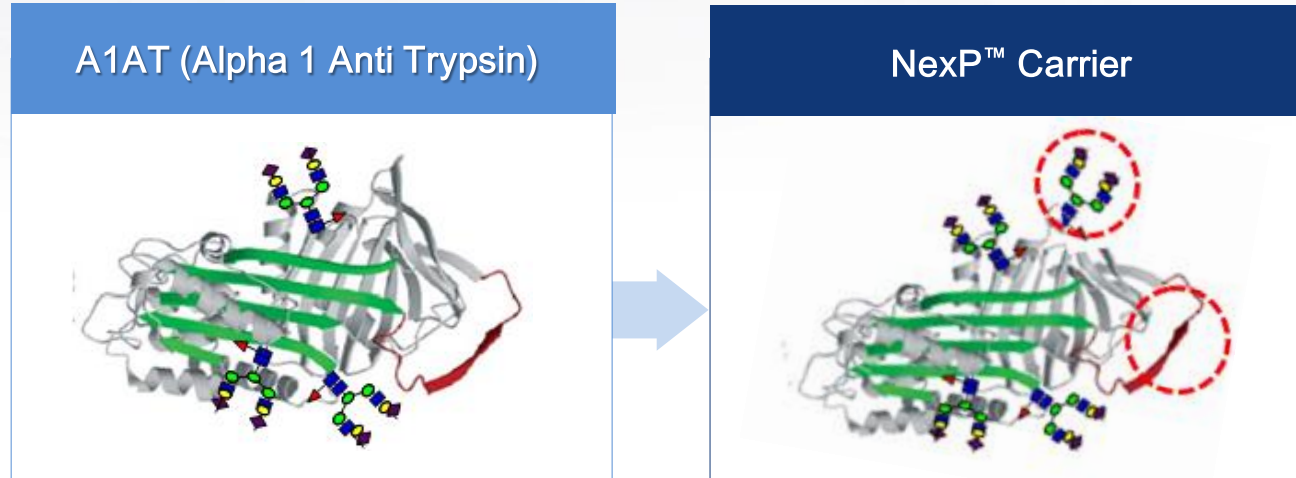
- Standalone Hyaluronidase product administered subcutaneously to reduce pain or swelling after dermal filler injection or surgeries
- Recombinant human hyaluronidase of higher purity (99%) offers a safer option compared to animal-derived products that contain foreign protein and have known side effects

Long-Acting Biobetters

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

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

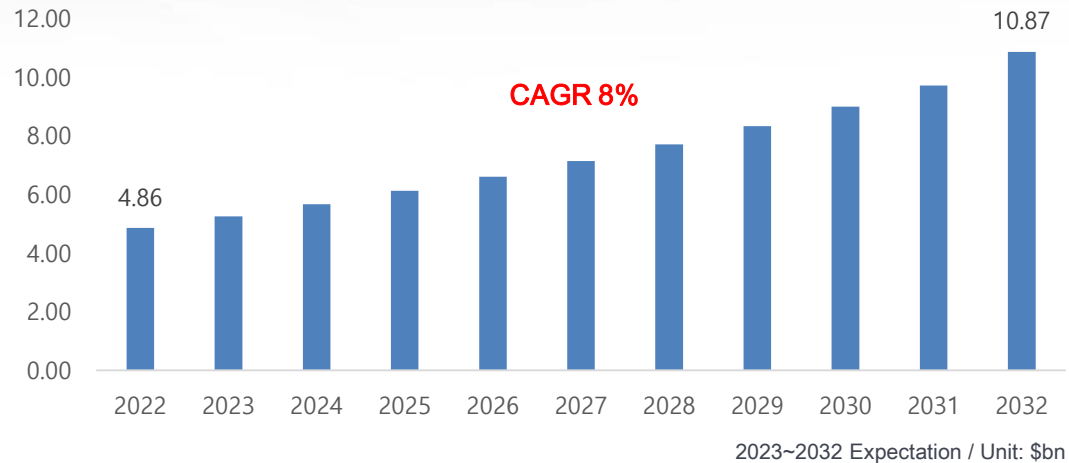
► Pipeline

- 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

Market / Plans for ALT-P1

Growth Hormone Global Market



- ✓ 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

Global Phase 2 for PGHD Patients

- ✓ Licensed-out to Cristália, Brazil in 2019
- ✓ 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 partnerships for territories except Latin America

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

Increasing Demand of Long-Acting Growth Hormone

Ultra-Long-Acting Platform Fusion Technology

A once-monthly formulation development

■ Current Treatment Landscape



Daily Injections → Weekly Injections

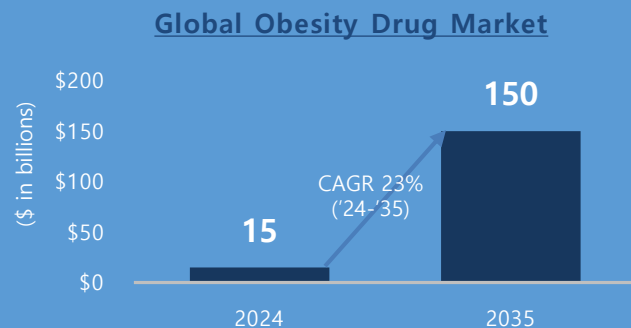
e.g. Saxenda (Q1D), Wegovy (Q1W), Zepbound (Q1W)



Daily Oral Pills

In development by pharmaceutical companies including Novo Nordisk

→ There is still an **unmet medical need for longer-acting obesity drugs to improve long-term adherence**



Source: Morgan Stanley (May 2025)

■ Novel Once-Monthly Treatment

- **Development strategies**

1. Discovering peptides against DPP-IV degradation
2. Validating long-lasting platform
3. Initiating clinical trials in 2027



- **PK results (SD rat)**

Sustainability

- Extended half-life compared to control

→ **Demonstrated feasibility of developing a long-acting drug formulation**

- **A PD study is ongoing in animals**

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



► 2024 global sales: US\$ 9.5B

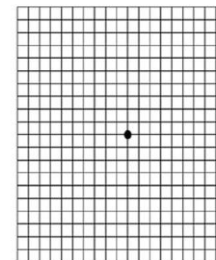
Drusen (deposits) causing
macula degeneration
(dry AMD)

8.7% of
World population
[WHO]

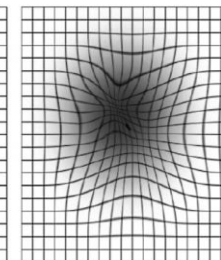
Abnormal new blood vessels
cause rapid and severe loss of
central vision (wet AMD)

~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-L2 Herceptin® BS Development by QiLu Pharmaceutical

China Herceptin® Market



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

2019 Sales Share

China / Global %

13.5%

2020 Sales Share

China / Global %

20.0%

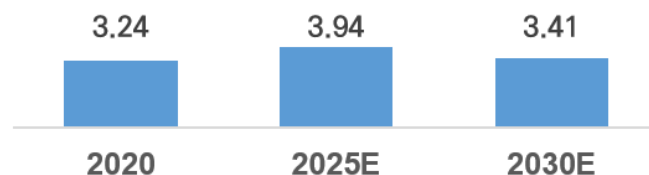
2020 Estimated
Access Rate in China

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 Received BLA approval from NMPA

2024 2H Commercialization in China

Alteogen Pipeline

Platform	Product	Process Development	Preclinical	Phase I	Phase II	Phase III	Registration	
Recombinant Hyaluronidase (Hybrozyme™)	ALT-B4 (SC Enabling)	MSD received FDA approval for subcutaneous Keytruda					Licensed to 6 partners First launch in 2025	
	ALT-BB4 (Single Agent)	Approved by MFDS					Approved & launched in 2024	
Biosimilar	ALT-L9* (wet AMD)	Approved by EMA					Approved in Europe in 2025	
	ALT-L2 (Breast & Gastric Cancers)	BLA approval from NMPA					Launched in China in 2024	
Long-acting Biobetter (NexP™)	ALT-P1 (Human Growth Hormone)	Domestic Ph2 completed for Adult Indication						
		Global Ph2 for Pediatric Indication					Led by Alteogen In Phase 2	
	ALT-B5 (Acromegaly)	Process Development					National Innovative Drug Development Program awarded 2021	
ADC (NexMab™)	ALT-P7 (Breast & Gastric Cancers)	Ph1 Completed in Korea					Combination therapy study	

* Co-developed with Alteogen Biologics, an Alteogen company



Thank you
for your attention!



www.alteogen.com