NOVEL BIOLOGICS FOR BETTER LIFE

ALTEOGEN

Company Introduction | Feb 2025

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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

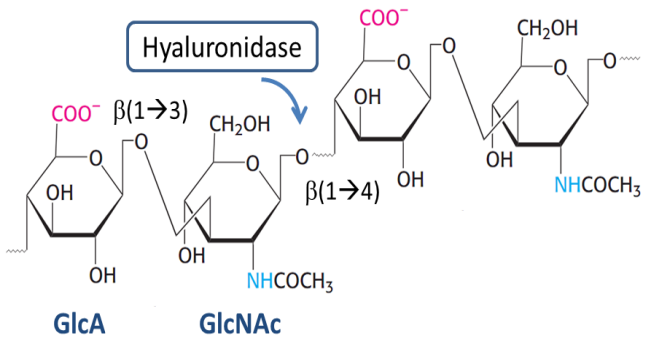
May 2008	Company founded
December 2014	Listed on KOSDAQ
November 2020	Altos Biologics established
February 2024	Alteogen Healthcare established
July 2024	Approval Tergase® by MFDS Submission of MAA to EMA for Eylea® biosimilar 'ALT-L9'

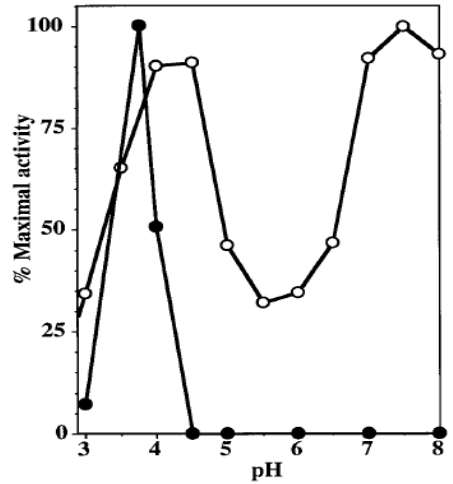
Hyaluronidase

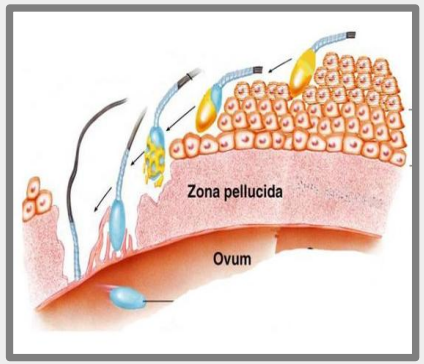
Enzyme Hydrolyzing Hyaluronan in Extracelluar Matrix

Five Human Hyaluronidases

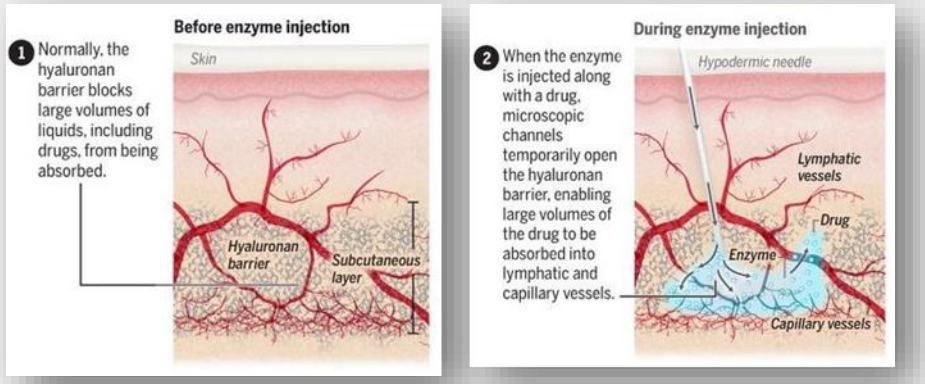
- Hyal1, Hyal2, Hyal3, and Hyal4: Optimum at pH 3
- PH20: Also active at pH 7~8







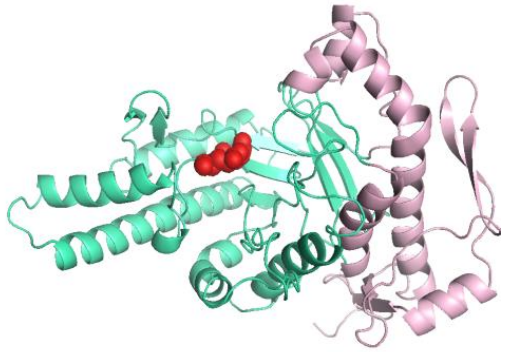
PH20 aids in penetrating the layer of cumulus cells



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

Introducing the Hybrozyme Platform

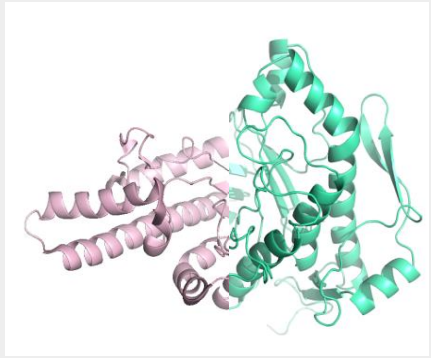
Alteogen's Main Business: Successful Development of an Improved PH20 Variant Using Domain Swapping Technology Enabling Subcutaneous Injection Formulation and Standalone Use



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, in vitro and in vivo* analysis
- Extensive patent coverage

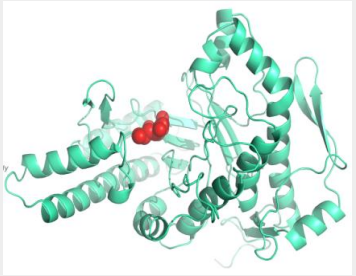


Generation of 〉300 chimeric variants
Extensive activity assay and other Physio–chemical assays

Best one called ALT–B4

Hyal 1

3D structure of Hyal 1 identified



PH20

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

Growing Need for Hybrozyme Platform

Expected Improvement in Therapeutic Effects

Lower IRR
Minimized Drug Side Effects

Expected Improvement in DCR, mPFS and OS

Economic Benefits

Reduced Medical Staff and Hospital Bed Usage Compared to IV
Increased Revenue for Medical Institutions
Reduced Patient Treatment Cost Burden
Lower Insurance Claims Pressure for Drug Adoption and Usage

Lower Development Costs and Higher Success Rate Compared to New Drug Development
Reduced Burden on Innovative Pharmaceutical Companies

Quality of Life Improvements

Enhanced Patient Quality of Life Through Increased Convenience

Lower IRR
Reduced Patient Discomfort

Reduced Treatment Time
Ability to Maintain Daily Activities
Possibility of Home Administration**

Patent Extension

Response to IV Biosimilar Launch, Market Conversion to SC Formulation Before Patent Expiry

Hyaluronidase Substance Patent

Formulation Patent for Combination of Therapeutic API and Hyaluronidase

Increasing Demand from Blockbuster Drugs Facing Patent Cliff

Emerging Need for SC Formulation Therapeutics with Hyaluronidase

Provides Benefits to All Stakeholders: Patients, Medical Institutions, Government, Insurance Companies, and Innovative Pharmaceutical Companies

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Longer Patent Duration Compared to Competitor

ALT-B4 US Patent Based on Hybrozyme Platform (~ 2043)

Platform Technology with Proven Safety

Validated Through Keytruda SC Formulation Phase 3 Clinical Trial Completion and Topline Results***

NCT01942135(PALOMA-3)*
NCT05340309**
https://www.merck.com/news/merck-announces-phase-3-trial-of-subcutaneous-pembrolizumab-with-berahyaluronidase-alfa-met-primary-endpoints/***

Major Licensing Agreements And Progress of Hybrozyme Platform

Hybrozyme™ Technology Licensing Agreements	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 an Exclusive License Agreement with **Daiichi Sankyo [Enhertu® '1st ADC SC']**

Global company for 2019 Agreement

Selection of development project

MSD

Revision of Agreement to exclusive to Keytruda ® (2024.02.24)
Completion of Keytruda ® SC Ph3
Targeting BLA by FDA approval and Launching in 2025*

Intas

Initiation of pivotal Ph1 of Biosimilar SC

Sandoz

Revision of Agreement for the development of multiple SC Biosimilars (2024.07.30)

Daiichi Sankyo/AstraZeneca

Agreement for Enhertu ® SC development (2024.11.08)

Robert Davis, Chairman & CEO of Merck & Co. Inc., JPMorgan Healthcare Conference Presentation, January 13, 2025.*

15 drugs selected for the Medicare Drug Price Negotiation Program for the 2nd cycle under IRA

ALT-B4, which is classified as an API by the FDA, the SC formulation is likely to be recognized as a new drug

Product Name	Active Ingredient	Company	FDA Approval Date
Ozempic	**Semaglutide**	**Novo Nordisk**	**05-Dec-17**
Wegovy			**04-Jun-21**
Rybelsus			**20-Sep-19**
Tradjenta	Linagliptin	Boehringer Ingelheim/Eli Lilly	02-May-11
Janumet	Sitagliptin/Metformin	MSD	30-Mar-07
Janumet XR			02-Feb-12
Trelegy Ellipta	Fluticasone/Umeclidinium/Vilanterol	GSK	18-Sep-17
Breo Ellipta	Fluticasone/Vilanterol		10-May-13
Xtandi	Enzalutamide	Pfizer/Astellas	31-Aug-12
Pomalyst	Pomalidomide	Bristol Myers Squibb	08-Feb-13
Ibrance	Palbociclib	Pfizer	03-Feb-15
Ofev	Nintedanib	Boehringer Ingelheim	15-Oct-14
Linzess	Linaclotide	AbbVie/Ironwood	30-Aug-12
Austedo	**Deutetrabenazine**	**Teva**	**03-Apr-17**
Austedo XR			**Feb-23**

- **The negotiated prices for drugs selected in the first cycle were reduced by 38% to 79%.**

- **Negotiated prices for initial price are applicable in 2027**
- **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: Ozempic(2017), Wegovy (2021) ⇒ Same API (Semaglutide)**

2024 Pipeline Progress Overview

	Application	Partner	in 2024
Hybrozyme™ Technology	Keytruda® SC *(1st Application)*	MSD	Announcement of Phase 3 clinical trial topline results
	Confidential (1st Application of Biosimilar SC)	Intas Pharmaceuticals	Initiation of pivotal Phase1 of Biosimilar SC
	Confidential (1st Application of Biosimilar SC)	Sandoz AG	*confidential*
	Enhertu® SC	Daiichi Sankyo/AstraZeneca	Signed License Agreement
	1st Application	*A company for 2019 Agreement*	Selection of development project
	Tergase® *(stand alone product)*	Alteogen healthcare (subsidiary)	Commercialization in Korea
Long acting Bio-better	ALT-P1 (Long-acting Hgh)	Cristália	Phase 2 Clinical Trial IND approval
	ALT-B5 (Long-acting Hgh antagonist)	-	Completion of nonclinical study
Biosimilar	安曲妥® (Trastuzumab biosimilar)	Qilu Pharmaceuticals	Commercialization in China
	ALT-L9 (Aflibercept biosimilar)	Altos Biologics (subsidiary)	Submission of MMA

Appendix

Application	Target	Company
HyQvia (2013)	IgG	Takeda
Herceptin SC (2013)	HER2	Roche
MabThera SC (2014)	CD20	Roche
Phesgo (2020)	HER2	Roche
Darzalex Faspro (2020)	CD38	J&J
Vyvgart SC (2023)	FcRn	Argenx
Tecentriq SC (2024)	PD-L1	Roche
Ocrevus SC (2024)	CD20	Roche
Opdivo SC (2024)	PD-1	BMS

Key Target Markets for Hybrozyme Platform

Blockbuster Drugs Facing Patent Cliff
High-Volume Oncology, Autoimmune Therapeutics
Therapeutic Areas with Existing Competition Licensing – ADCs, bispecific and Trispecific Antibodies

Thank you for your attention!

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