



AnGes

FY2022 Financial Results Materials

— Leading Global in Gene Medicine —



February 2023

- ◆ The performance forecasts and forward-looking statements in these materials are based on information currently available to the Company and include potential risks and uncertainties.
- ◆ These risks and uncertainties include changes in the economic environment surrounding the Company, progress with research and development, the approval of acquisitions by the regulatory authorities, and system changes and revisions to laws and regulations in countries around the world.
- ◆ Actual business performance and results may differ significantly from the described forecasts due to various factors.

This document has been translated from the Japanese original for reference purposes only.
In the event of any discrepancy between this translation and the Japanese original, the original shall prevail.

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About AnGes

VISION & MISSION



AnGes aims to become a global leader in genetic medicine.

We focus on research and development of the next-generation biopharmaceuticals such as genetic medicines and aim to achieve practical use of innovative drugs.

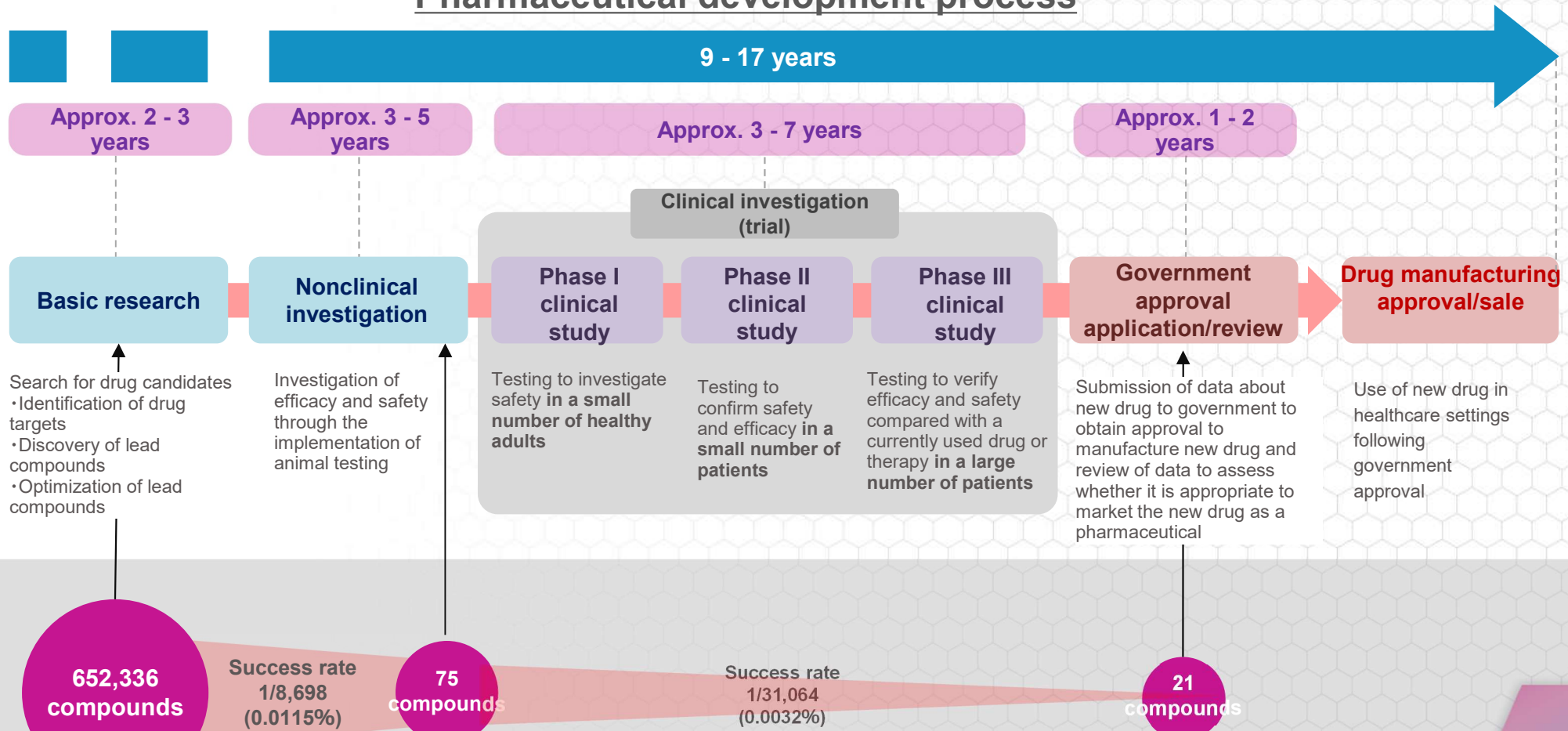
It is our mission to make a contribution to the improvement of people's Quality of Life (QOL) and medical standards through the development of innovative drugs. This is accomplished by utilizing advanced technology for the creation of next-generation biopharmaceuticals such as genetic medicines and therapeutic vaccines for **diseases that are intractable or rare, and for which no treatments available.** We are dedicated to **providing innovative drugs for patients as promptly as possible.**

New Drug Development Pathway

The success rate of new drug development is low and the degree of difficulty is extremely high!

The odds of a compound being launched as a new drug is approximately one in every 30000 shots (0.003%)

Pharmaceutical development process



(Reference)
<https://www.kantei.go.jp/jp/singi/kenkouiryou/iyakuhin/dai1/siryu2-5.pdf>

02

Summary of Financial Results for FY2022

Highlights of Consolidated Results for FY2022

Item (Million yen)	FY2021	FY2022	Increase/decrease
Business Profit	64	67	+3
Business Expenses	15,696	16,383	+687
Operating Profit	-15,632	-16,316	-684
Non-operating income/expenses	+2,043	+1,706	-337
Ordinary Profit	-13,588	-14,610	-1,022
Extraordinary income/losses	-146	-107	+39
Profit	-13,675	-14,714	-1,039

Business revenues (+4.5% YOY)

Collategen sales: ¥11 million (¥34 million in FY2021)
Contracted testing at ACRL: ¥55 million (¥29 million in FY2021)

Business expenses (+4.4% YOY)

Cost of sales: ¥93 million (¥56 million in FY2021)
Research and development expenses: ¥10,999 million (¥10,783 million in FY2021)

- Increase in development expenses for genome editing at EmendoBio
- Research and development expenses decreased following completion of the COVID-19 vaccine clinical trial

Selling, general and administrative expenses: ¥5,290 million (¥4,855 million in FY2021)

- Amortization of goodwill: ¥2,883 million (¥2,407 million in FY2021)

Impacted by weak yen despite the same number of US dollar-denominated depreciation as FY2021.
Average exchange rate for \$1 USD to ¥1 JPY was ¥131.64 in FY2022 and ¥109.90 in FY2021.

Non-operating income/expenses

- Subsidy income: ¥393 million (¥1,500 million in FY2021)
- ¥118 million for COVID-19 vaccine development (¥1,400 million in FY2021) and ¥276 million for Vasomune (¥100 million in FY2021)
- Foreign exchange gains due to revaluation of foreign currency-denominated assets: ¥1,322 million (¥599 million in FY2021)

Dec. 31 2022 \$1 USD = ¥132.70 JPY
Dec. 31 2021 \$1 USD = ¥115.02 JPY (yen depreciated by ¥17.68 YOY)

Extraordinary income/Extraordinary losses

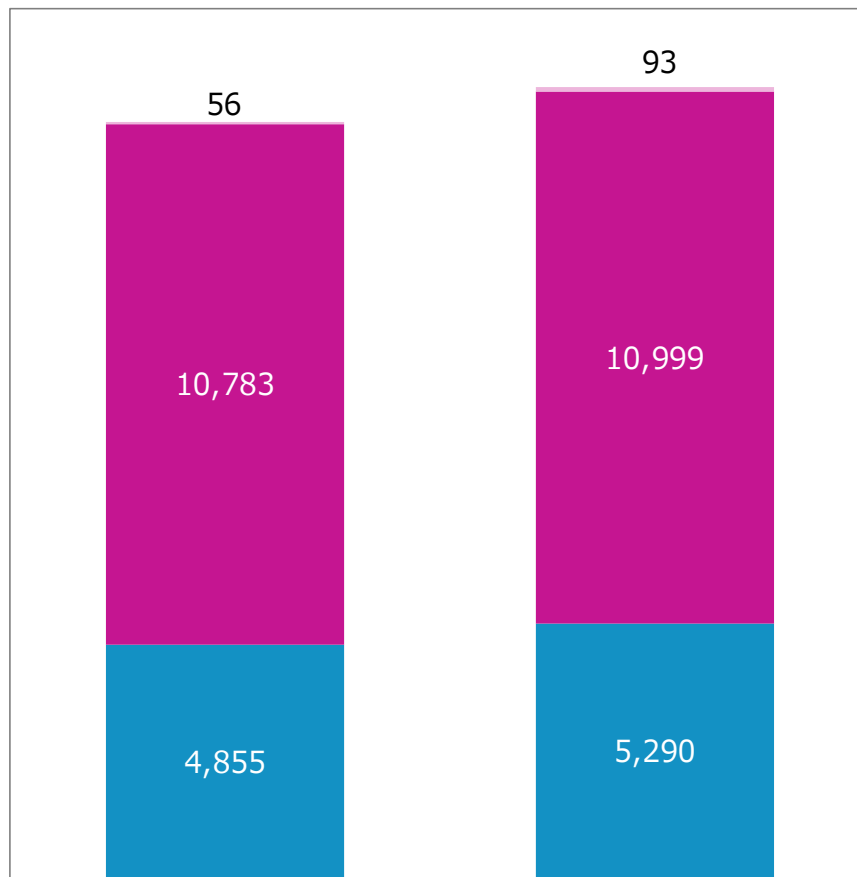
- Impairment losses on non-current assets: ¥104 million (nil in FY2021)
- Loss on valuation of investment securities: ¥6 million (¥179 million in FY2021)

Details of Business Expenses

(Unit : Million Yen)

Total business expenses
¥15,696million

Total business expenses
¥16,383million



FY2021

FY2022

■ Selling, general and administrative expenses
■ Research and Development expenses
■ Cost of sales

Cost of sales: ¥93 million

(+¥37 million / +65.5% YOY)
Inventory write down for Collategen with reaching of expiry date

Research and development expenses: ¥10,999 million

(+¥215 million / +2.0% YOY)
 1. Research material costs: ¥1,957 million (-¥276 million YOY)
 Research material costs decreased following the completion of the COVID-19 vaccine clinical trial
 2. Outsourcing expenses: ¥5,905 million (+¥354 million YOY)
 Outsourcing expenses increased due to expansion of clinical trials for Tie2 receptor agonists
 3. Salaries and allowances: ¥1,102 million (+¥286 million YOY)
 Increase in number of EmendoBio employees (researchers)

Selling, general and administrative expenses: ¥5,290 million

(+¥434 million / -9.0% YOY)
 1. Commission expenses: ¥855 million (-¥103 million YOY)
 EmendoBio-related consulting expenses decreased
 3. Amortization of goodwill: ¥2,883 million (+¥476 million YOY)
 Increase in depreciation associated with weak yen (average exchange rate for \$1 USD to ¥1 JPY was ¥131.64 in FY2022 and ¥109.90 in FY2021)
 (Increase due to revaluation of US dollar-denominated goodwill in yen)

Consolidated Balance Sheet Highlights

Item (Million yen)	Dec. 31, 2021	Dec. 31, 2022	Increase/decrease
Current assets	21,426	12,896	-8,530
Cash and deposits	17,899	11,035	-6,864
Non-current assets	24,029	25,924	+1,895
Goodwill	22,675	23,254	+579
Total assets	45,455	38,820	-6,635
Liabilities	6,821	8,395	+1,574
Net assets	38,634	30,425	-8,209

Current assets

- Cash and deposits: ¥11,035 million (-¥6,864 million YOY)
Decrease due to business expenditures. Raised capital of ¥3,589 million
- Advance payments to suppliers: ¥303 million (-¥1,410 million YOY)
Decrease due to the transfer of expenses related to COVID-19 vaccine production

Non-current assets

- Balance of goodwill: ¥23,254 million (+¥579 million YOY)
Balance increase attributed to a ¥3,461 million revaluation gain associated with the weak yen, despite ¥2,883 million in depreciation (based on 10 years)
(Net assets are treated as foreign currency translation adjustments)
- Lease accounting standard is applied (the US accounting standard of EmendoBio)
Right of use assets: ¥1,318 million (nil in FY2021)

Liabilities

- Advances received: ¥5,764 million (+¥644 million YOY)
Increases in subsidies for COVID-19 vaccine development from AMED and the Ministry of Health, Labour and Welfare
- Application of lease accounting (US accounting standard of EmendoBio)
Lease liabilities: ¥1,155 million (nil in FY2021)

Net assets

- Share capital / capital surplus from financing: ¥1,786 million
- Decrease of ¥14,714 million in retained earnings due to net loss
- Revaluation gain due to weak yen
Foreign currency translation adjustment: ¥4,841 million (+2,937 million YOY)

Earning Forecast for FY2023

(Unit : Million Yen)

	Business Revenues	Operating Profit	Ordinary Profit	Profit
FY2023 full-year plan	190	-15,500	-9,900	-10,000
FY2022 full-year results	67	-16,316	-14,610	-14,714
Increase / decrease	123	816	4,710	4,714

Subsidies received in FY2022 for the development of DNA vaccines for COVID-19 were recorded as advances received. We plan to record these subsidies as non-operating income in the FY2023 full-year forecast.

03

Development Pipeline: Topics

Status of Projects in the Clinical Development Stage

■ Conditional and time-limited approval system

Project	Area	Licensee/partner	Dosage form	Indications	Basic research	Preclinical study	Clinical investigation (trial)		Approval/review	Conditional/time-limited approval	Sale	Post-marketing surveillance	Formal approval
							Phase I	Phase II					
HGF gene therapy product	Japan	Mitsubishi Tanabe Pharma	Injectable	Chronic arterial occlusive disease with lower limb ulcer	▶	▶	▶	▶	▶	Approved	On Sales	On going	<p>NEW</p> <p>Completed administration in target number of patients Preparing for application</p>

■ Approval Process

Project	Area	Licensee/partner	Dosage form	Indications	Basic research	Preclinical study	Clinical investigation (trial)			Approval/review	Approval
							Phase I	Phase II	Phase III		
	United States	Mitsubishi Tanabe Pharma	Injectable	Arteriosclerosis obliterans with lower limb ulcer	▶	▶	▶	P2b (on going)			<p>NEW</p> <p>Completed administration in target number of patients</p>
HGF gene therapy product	Israel	Kamada	Injectable	Chronic arterial occlusive disease with lower limb ulcer	▶					Application	
	Turkey	Er-Kim	Injectable	Chronic arterial occlusive disease with lower limb ulcer	▶					Preparig for application	
NF-κB decoy oligonucleotide DNA	US / Japan	—	Injectable	Chronic discogenic lumbar back pain	▶	▶	Completed				<p>NEW</p> <p>Preparing for Phase II in Japan</p>
DNA vaccine	Australia	—	Injectable	Hypertension	▶	▶	Completed				
DNA vaccine	Inside and outside Japan	—	Injectable	COVID-19 / ADRS	▶	▶	Underway				
Tie-2 receptor agonists	United States	Vasomune	Injectable		▶	▶	Completed	P2b (on going)			
Zokinvy (lonafarnib)	Japan	Eiger (Origin of in-licensing)	Capsule	Progeria (HGPS·PL)	In-licensed product					Preparig for application	

Development Status of HGF Gene Therapy Product

Gene therapy drug for angiogenesis Collategene®, HGF Gene Therapy Product

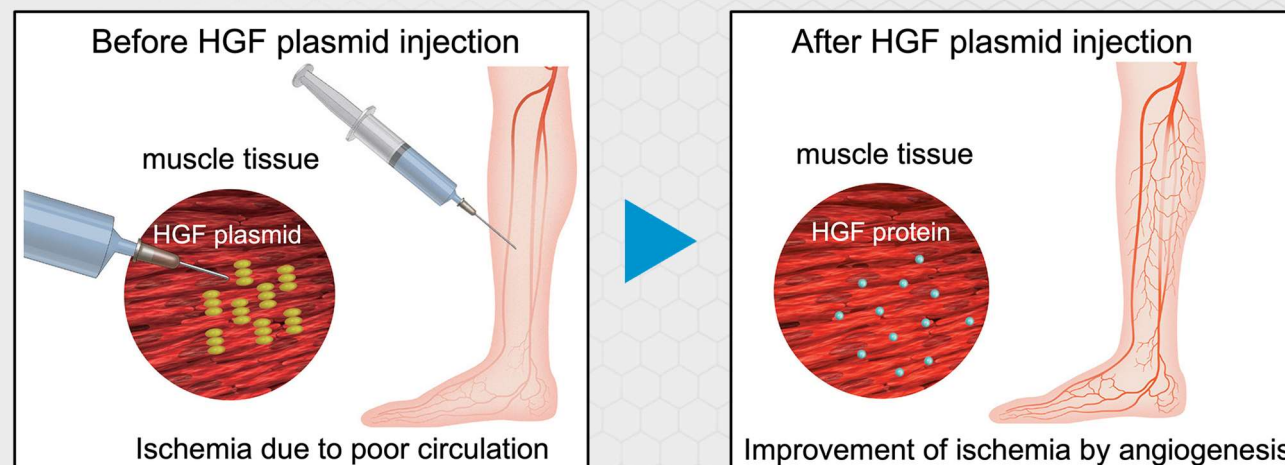
AnGes successfully commercialized an HGF gene therapy Product based on plasmid DNA for the first time in the world in 2019.

- 1) **Japan's first** gene therapy product
- 2) **The world's first** plasmid (DNA molecule) product
- 3) **The world's first** practical application of HGF
- 4) **The world's first** therapeutic product forming new peripheral vessels
- 5) **The world's first** therapeutic product in the field of cardiovascular medicine

Approval criteria of the following three organizations:
- Food and Drug Agency (FDA), USA
- European Medicines Agency (EMA)
- Ministry of Health, Labour and Welfare (MHLW), Japan

The information above is as of March 2019 when we obtained a conditional and time-limited manufacture and sales approval.

Angiogenesis by an HGF Gene Therapy Product



Preparation for application in spring 2023 for this approval (As of December 2021, 120 cases have been administered)



Applicable disease	Ulcers associated with chronic arterial occlusive diseases (The condition is that blood vessels are completely obstructed and blood flow is blocked, causing a shortage of nutrients and oxygen hindering the healing of even minor scars, and ischemic ulcers and necrosis occurs.)
Number of patients	800,000 patients with chronic arterial occlusive disease in Japan (source: IMS Health, survey materials)
Development status	Launched by Mitsubishi Tanabe Pharma on September 10, 2019. The goal is to receive formal approval within five years (by 2024) based on results of the post-marketing surveillance of 120 patients. (Administration to 120 patients completed as of December 2021)

September 2019: Launched by Mitsubishi Tanabe Pharma

February 2019: Conditional and time-limited approval of the Working Group's Meeting on Regenerative Medicine and Biological Technology under the Pharmaceutical Affairs and Food Sanitation Council, Ministry of Health, Labour and Welfare

January 2018: Application for approval to manufacture and sell the drug submitted to the Ministry of Health, Labour and Welfare

2015: An exclusive domestic distribution rights licensing agreement for the product with the indication for peripheral vascular disease signed with Mitsubishi Tanabe Pharma.

Late Phase II clinical study underway in the USA.



Applicable disease	Ulcers associated with chronic arterial occlusive diseases
Number of patients	Obstructive arteriosclerosis: 7,780,000 (USA) (Source: Foster Rosenblatt, survey materials)
Development status	Late Phase II clinical study underway in the USA (from February 2020) Enrollment of 60 cases completed (end of 2022)



2022: Kamada Ltd submitted a marketing authorization application to the Israel Ministry of Health, which was accepted.

2020: A basic agreement on the licensing-out (of exclusive distribution rights) for Turkey signed with Er-Kim.

Late Phase II study underway in the USA under the new guidelines (Global Vascular Guideline).

2019: A basic agreement on the licensing-out (of exclusive distribution rights) for Israel signed with Kamada

2012: An exclusive distribution rights licensing agreement in the USA for the product with the indication for peripheral vascular disease signed with Mitsubishi Tanabe Pharma.

Development Status of NF- κ B decoy oligonucleotide DNA

We are developing NF- κ B decoy oligonucleotide DNA for the treatment of intervertebral lumbago.

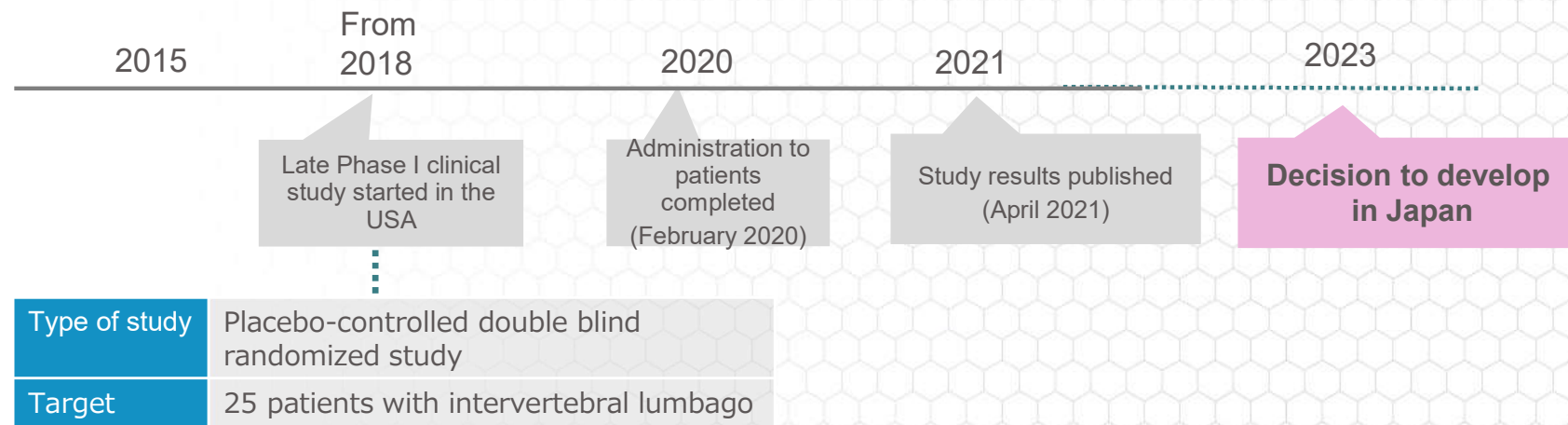
NF- κ B is the major transcription factor that is activated due to inflammatory and immune reactions in cells when external stimuli are present, such as oxidative stress from active oxygen, in the case of the activation of inflammation or immunity.

It has been pointed out that it will exacerbate allergic/immunological diseases such as atopic dermatitis and asthma if NF- κ B over-activates an inflammation-causing gene.

When a large amount of NF- κ B decoy is put in the body as a decoy, **it will inhibit binding between NF- κ B and the genetic transcriptional regulatory sequence that causes inflammation.**

We have been developing this drug since 2018 for the treatment of low back pain, including discogenic back pain

Decided to conduct Phase II clinical trials in Japan



Applicable disease	Chronic discogenic lumbar back pain
Number of patients	5,770,000 (USA) (Source: https://hpi.georgetown.edu/backpain and Pain Med. 2015,16(8):1490-9)
Development status	Administration to 25 patients in the late Phase I clinical study completed in the USA (February 2020). Decision to conduct Phase II clinical study in Japan (January 2023)

Jan 2023: Decision to conduct Phase II clinical study in Japan.



April 2021: Results of the late Phase I clinical study (observation period: 12 months) published.

February 2021: Results of the late Phase I clinical study (observation period: 6 months) published.

February 2020: Administration to 25 patients completed.

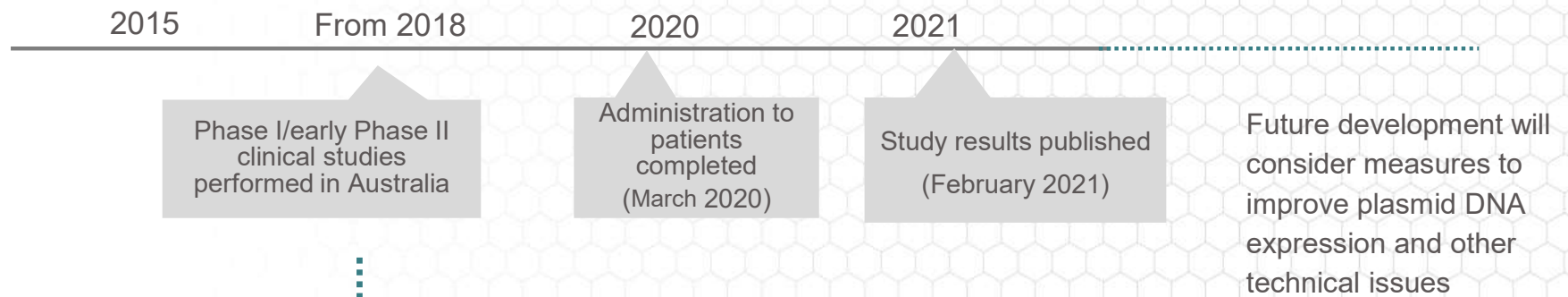
February 2018: Late Phase I clinical study started in the USA

Note: The global market size is large, including the USA

Note: Treatment with intervertebral injection is common in the USA. There are many doctors proficient in the technique, and the number of patients is high in the country.

Development Status of DNA Vaccine for Hypertension

Administration to patients in Phase I/early Phase II clinical studies completed. Future development will include measures to improve technical issues



Type of study	Placebo-controlled double blind randomized study
Target	24 patients with hypertension

Applicable disease	Hypertension
Number of patients	61,460,000 (USA) (Source: AHA (https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000757))
Development status	Administration to patients in Phase I/early Phase II clinical studies completed (March 2020) Study results published (no serious adverse events, no problem with safety) Under preparation for the start of the next stage of clinical investigation.

February 2021: Results of Phase I/early Phase II clinical studies published.

March 2020: Administration to patients in Phase I/early Phase II clinical studies completed.

Safety and efficacy to be evaluated in a double-blind setting for about 6 months.

Then, long-term safety and efficacy in an open-label setting for about 6 months.

April 2018: Phase I/early Phase II clinical studies started in Australia.

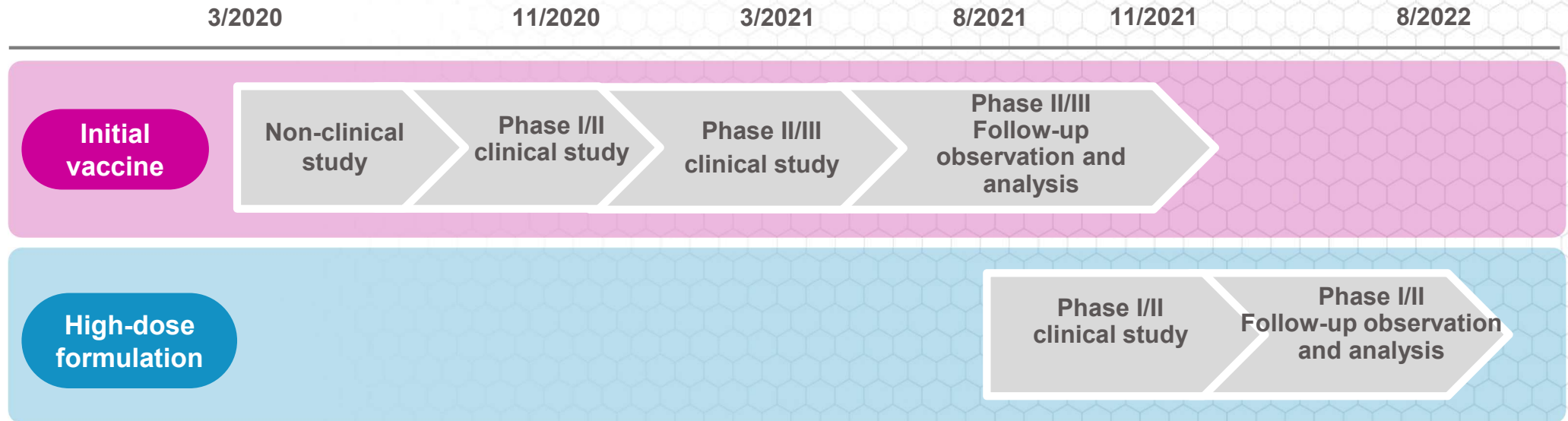
Development Status of Covid-19 Coronavirus DNA Vaccine

Development of DNA vaccines up to this point was discontinued, and an improved DNA vaccine was newly developed



After deciding to develop a DNA vaccine for COVID-19 (Wuhan strain) in March 2020, we began non-clinical testing of the initial vaccine and completed administration of the Phase II/III clinical study by March 2021. Phase I/II clinical study using a high-dose formulation of the initial vaccine with an increased drug concentration began in August 2021.

No safety problems were observed, and although some increase in cellular immunity was confirmed, the expected effect could not be obtained for liquid immunity, and the decision was made to discontinue the development of DNA vaccines up to this point.



DNA vaccines up to this point



Initiative with Stanford University

Research and development of nasal dosage forms for safer and more effective vaccines

Improved DNA vaccine

Platform review

Improved plasmid expression and transduction efficiency

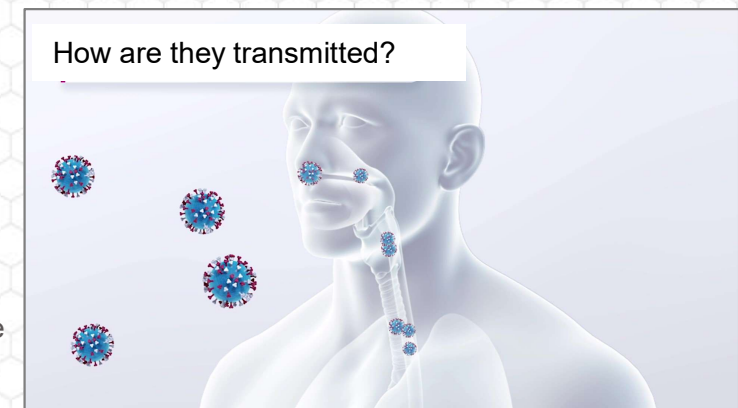
Nasal dosage forms

Stimulates a broad immune response, preventing viral proliferation and spread

[About nasal administration]

Viruses and bacteria that cause COVID-19, influenza, and colds try to enter the body through the mucous membranes of the “upper respiratory tract” such as the nose, mouth and throat, and the “digestive tract” such as the intestinal tract. The upper respiratory tract and digestive tract have a mechanism called “mucosal immunity” to protect against infection and intercept viruses.

If antibodies known as “IgA” of the type secreted in the mucous membranes can be produced in the nose and throat, it may be more effective in preventing the infection itself, and nasal administration can create immunity in the respiratory tract, which is the site of infection.

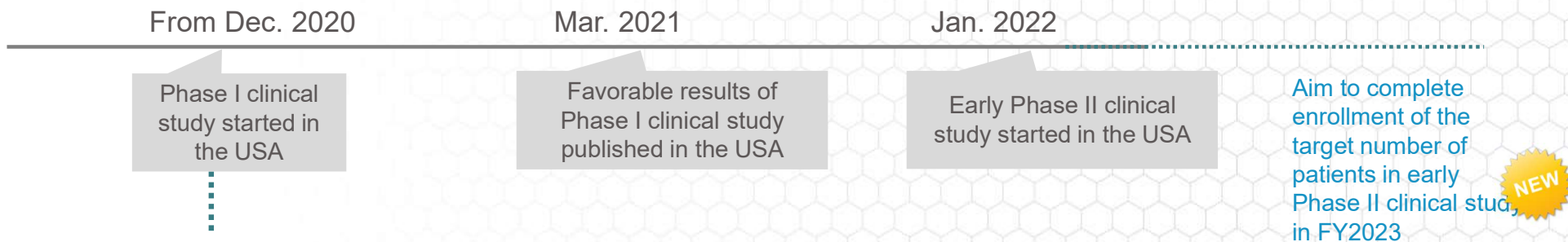


■ Outline of joint research agreement

Name of partner	Stanford University
Location of partner	California, United States
Research duration	Approximately 3 years
Research fund	Approximately 3 million USD

Tie-2 Receptor Agonist

Early Phase II clinical study underway



Type of study	Placebo-controlled double blind study
Target	Healthy adults

Applicable disease	Acute respiratory distress syndrome associated with COVID-19
Number of patients	Acute respiratory distress syndrome: 260,000 (USA) (Source: Am J Resp Crit Care Med, Volume 195 Number 7)
Development status	AV-001, Tie-2 receptor agonist compound Early Phase II clinical study underway in the USA Submitted an application to the FDA (U.S.) and received approval to expand the target disease to ARDS, including viral and bacterial pneumonia such as influenza.



March 2021: Favorable results of the Phase I clinical study with the drug for treating COVID-19 AV-001 published in the USA.
 Vasomune obtained a subsidy from the Canadian government for development of AV-001, the drug for treating COVID-19

December 2020: Phase I clinical study with the drug for treating COVID-19 AV-001 started in the USA.
 Safety and tolerability of AV-001 confirmed in the Phase I clinical study.

July 2018: Joint development of AV-001 with Vasomune Therapeutics (Canada) started.
 Target diseases: Diseases caused by insufficiency of blood vessels, such as acute respiratory failure

The background of the slide features a white hexagonal grid pattern. In the top right corner, there is a network diagram with nodes and connecting lines. In the bottom right corner, there is a purple and blue gradient shape.

Zokinvy[®],
a Drug for Treating Rare Diseases
(Lonafarnib)

Aiming for regulatory approval and listing in the NHI drug price list, preparations are underway to obtain approval in Japan

May 2022

Signed a distribution agreement with Eiger for Zokinvy in Japan

Aiming for regulatory approval and NHI drug price listing as soon as possible
First, we will proceed with procedures to receive orphan drug designation

*About orphan drug

Rare disease drugs for intractable diseases for which the number of patients is small and treatment methods have not been established
The revision of the Pharmaceutical Affairs Law in 1993 started a full-fledged public R&D assistance program for orphan drugs.

Target disease

Hutchinson-Gilford Progeria Syndrome (HGPS)/Progeroid Laminopathy (PL) (Progeria)

Status

In preparation for orphan drug designation
Meetings with relevant agencies for approval in Japan

May 2022: Entered into an agreement with U.S. pharmaceutical company Eiger BioPharmaceuticals Inc. to market Zokinvy, a rare disease therapeutic, in Japan.

AnGes Clinical Research Laboratory (ACRL)

AnGes Clinical Research Laboratory (ACRL)



They are a health laboratory whose main purpose is to perform testing for rare genetic diseases

Rare genetic diseases

- Ultra-rare diseases with very small number of patients (e.g., phenylketonuria, mucopolysaccharidosis, duchenne muscular dystrophy)
- It is important to start treatment in the early stages after onset and ideally before onset.

AnGes Clinical Research Laboratory



We have been contracted to provide testing services for optional screening, fee-based testing provided by the Clinical & Research Association for Rare, Intractable Diseases (CReARID) for people who wish to be tested.

- Established in April 2021
- Optional screening started in cooperation with CReARID. (July 2021)
- Today, about 10,000 tests are performed per year.
- We will enhance tests to test for more diseases and increase the number of test labs in the future.

Tests for newborns

Mass screening

- Provided free to all babies born in Japan (e.g., phenylketonuria, congenital hypothyroidism)

Fee-based additional tests

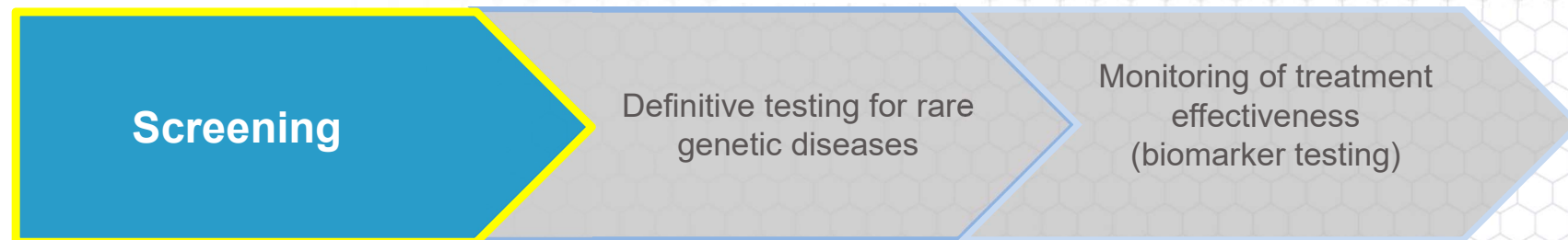
- Fee-based tests provided to applicants
- Diseases excluded from mass screening (e.g., Pompe disease, mucopolysaccharidosis)

AnGes Clinical Research Laboratory (ACRL)



Establishment of a **system that enables comprehensive testing from diagnosis to treatment** of rare genetic diseases, including definitive testing for rare genetic diseases and biomarker testing to monitor treatment effectiveness

At present



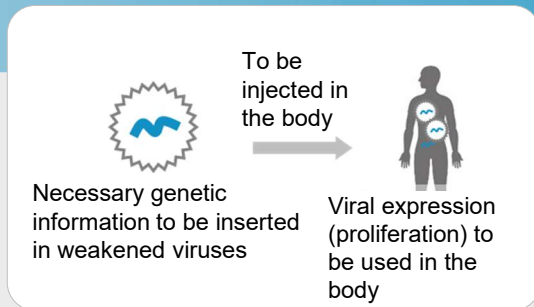
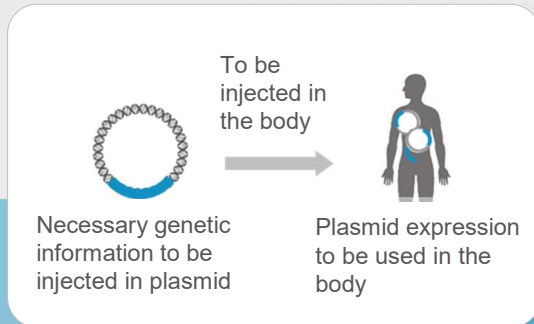
From now



Genome Editing Development Status at EmendoBio

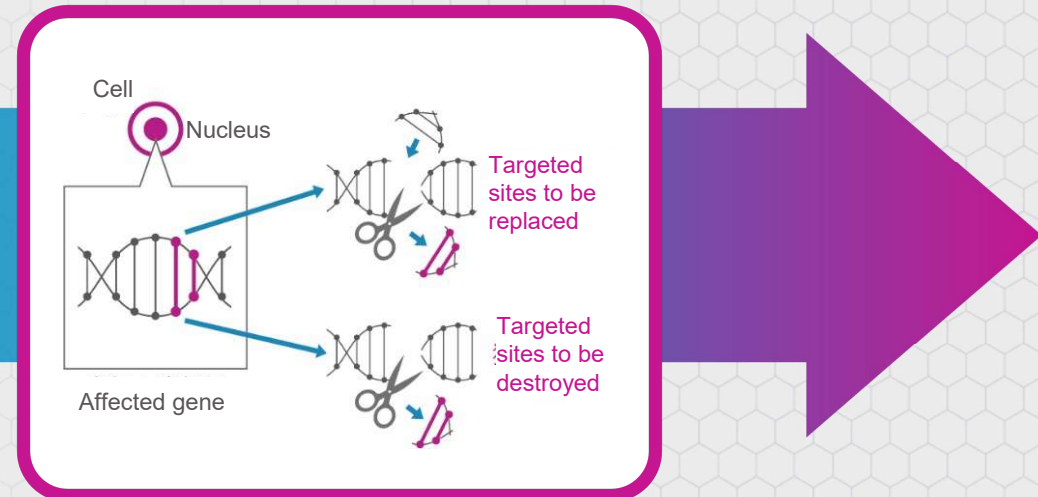
The Stage Following Gene Therapy

Plasmid DNA



Viral vector

Genome Editing



Genome editing is the ultimate gene therapy

What is Genome Editing?

The technology uses nuclease, the enzyme for cleaving DNA that selectively cuts off specific base sequences (target sequences).

★ CRISPR/Cas9

(Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR-Associated Proteins 9)

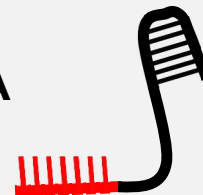
In 2012, an innovative technology was developed for cleaving target DNA sequences more quickly and easily than the conventional technologies.

1) Read a base sequence.

A T G C T T A A G C T
T A C G A A T T C G A

2) Identify a specific site.

Guide RNA

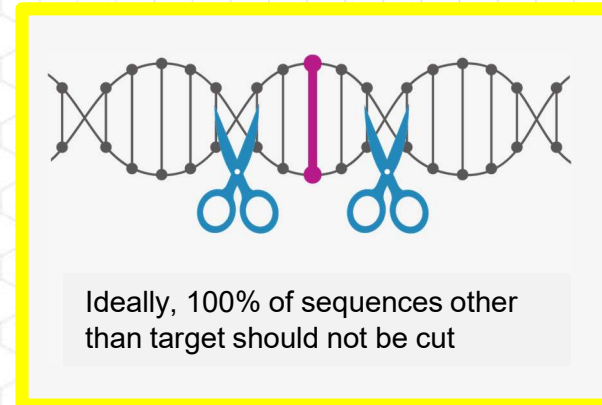
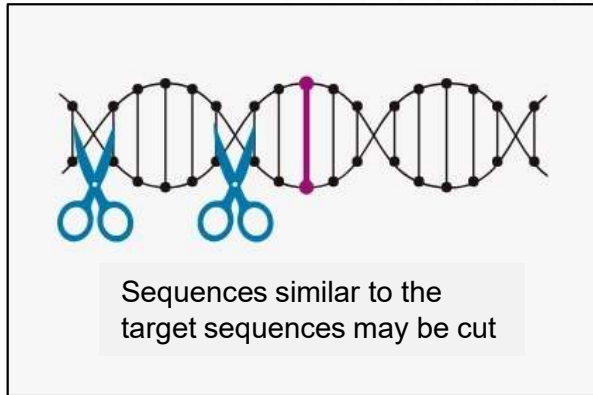


3) Cut off a specific part at a place where nuclease is guided
Nuclease
(Enzymes)



Genome editing won the Nobel Prize in Chemistry in 2020.
The technology is attracting global attention, and is expected to be applied in humans.

emendo^{bio} For the Avoidance of Off-target Effects



It is important to avoid off-target effects

To mitigate off-target effects:

- Search for any sequences similar to target sequences in genomes.
- Avoid target sequences if there are similar ones. Look for other target sequences.

"Off-target effects" was a concern for conventional technologies. Emendo, however, aims to establish highly safe genome editing and apply the technology in healthcare using an improved nuclease.

OMNI nuclease

1) Read a base sequence.

ATGCTTAAGCT
TACGAATTCGA

2) Identify a specific site.

Guide RNA



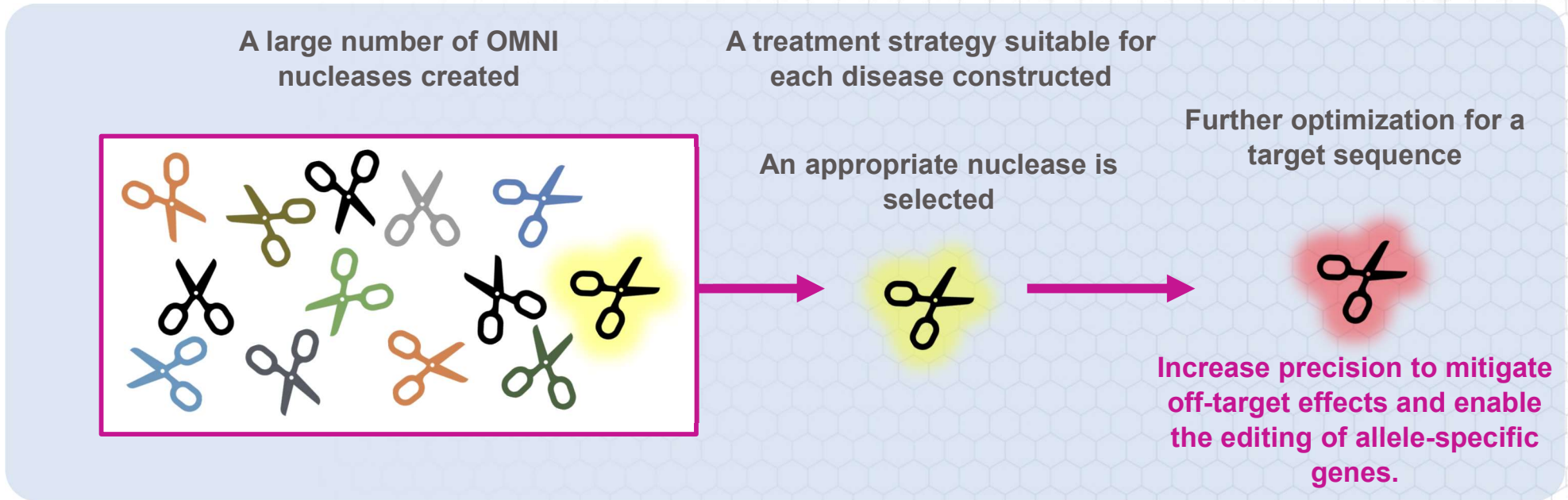
3) Cut off a specific site **with higher precision** at a place the nuclease is guided to.

The original nuclease (enzyme)



Original search technology
(development platform) established

Mitigation of off-target effects enabled



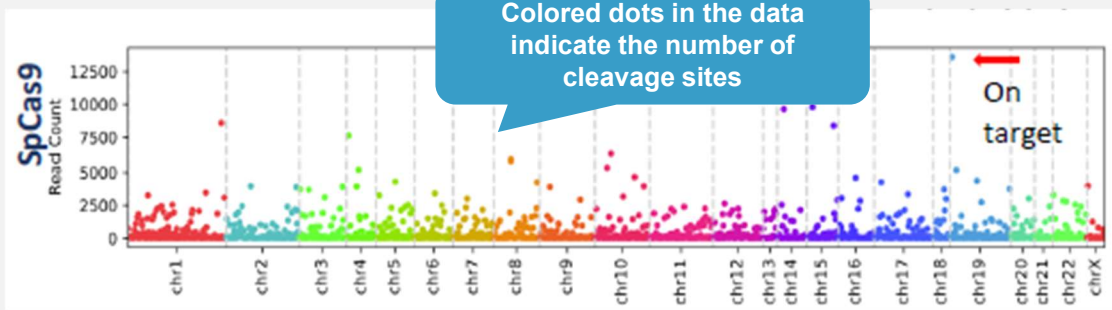
Establishment of the OMNI Platform

Emendo creates a large number of OMNI nucleases with new characteristics, selects the appropriate nucleases from many OMNI nucleases, and optimizes them for the target sequences. They are developing safe and effective remedies, exploring new nucleases and using optimization technology.

CRISPR/Cas9

(Nobel Prize in Chemistry 2020)

In addition to on-target sites, a significant number of **off-target sites** are seen quite frequently

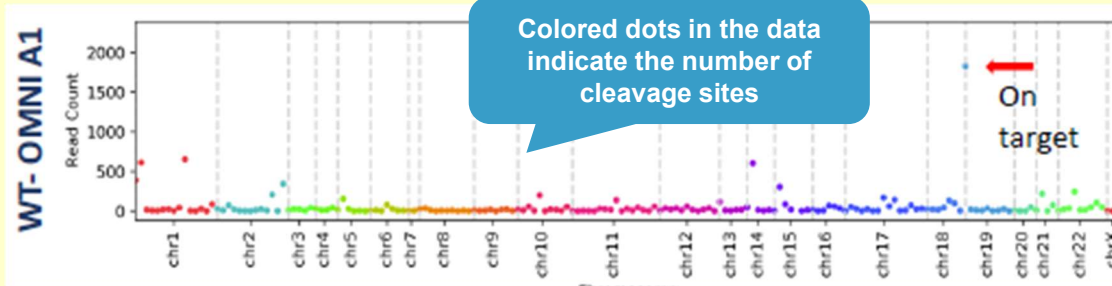


EmendoBio's genome editing technology

Wild-type OMNI-A1

(Before optimization)

Off-target sites are much less common, but there are scattered cleavage sites other than on-target sites

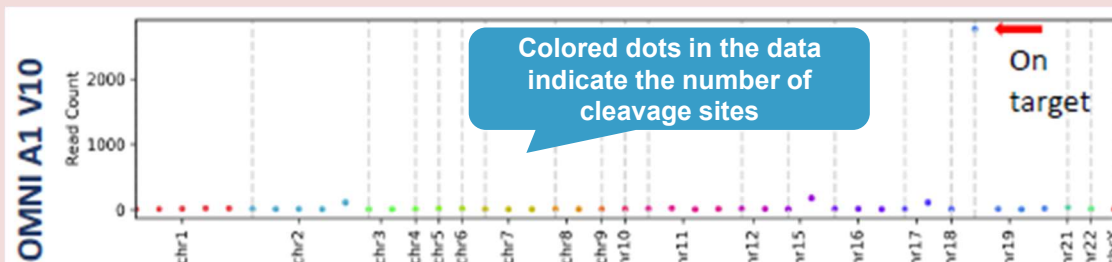


Optimization (Further optimization of allele-specific gene editing with AI)

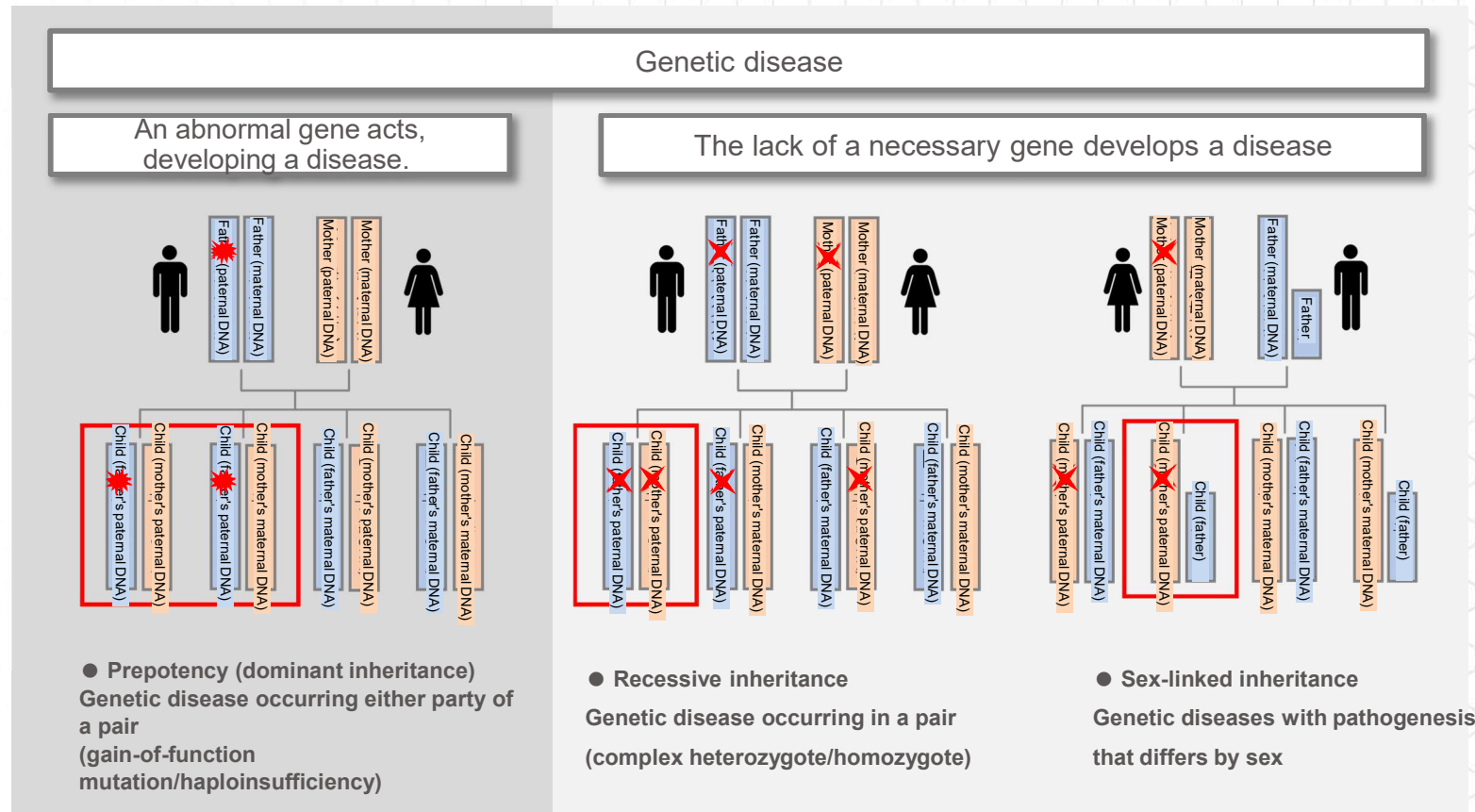
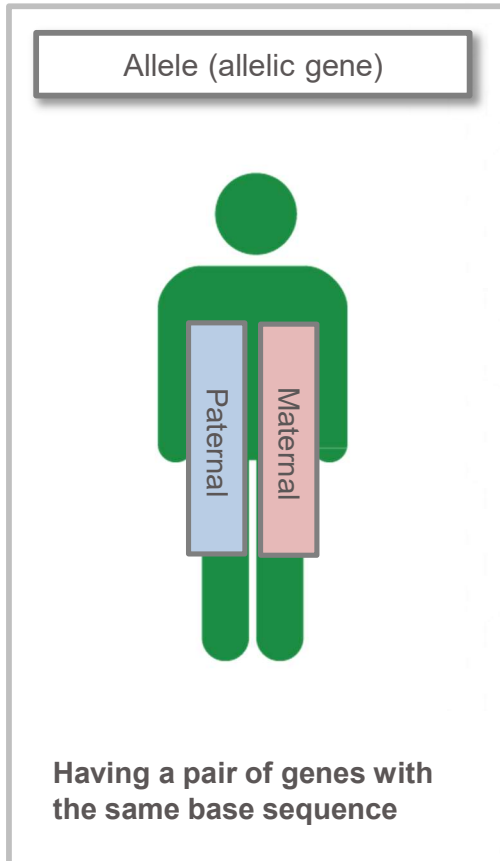
OMNI-A1-V10

(After optimization)

Almost no cutting occurs except for on-target (disease-causing) areas
 ⇒ No extra cuts are made except where cuts should be made

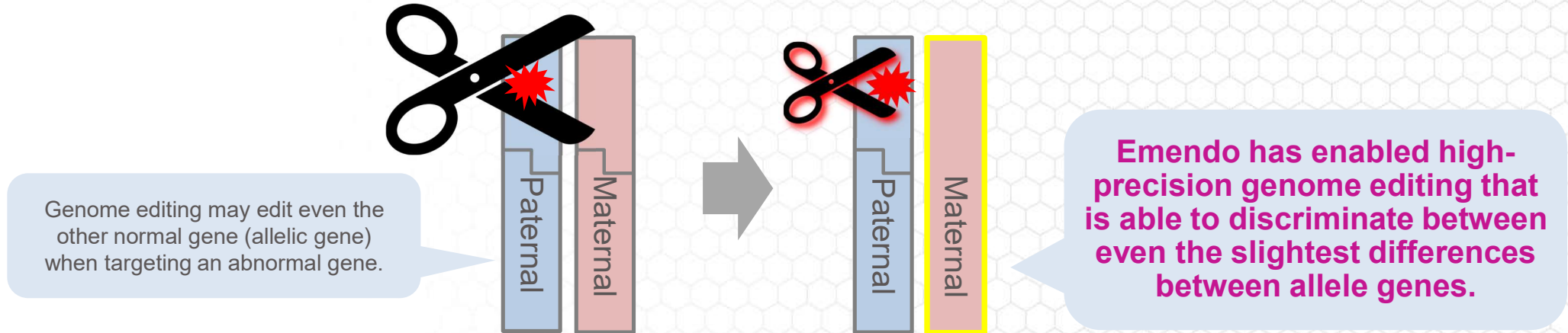


Basically, a human has a pair of genes with the same base sequence.



Genetic diseases can occur if both paternal and maternal genes are abnormal or either the paternal or maternal gene is abnormal.

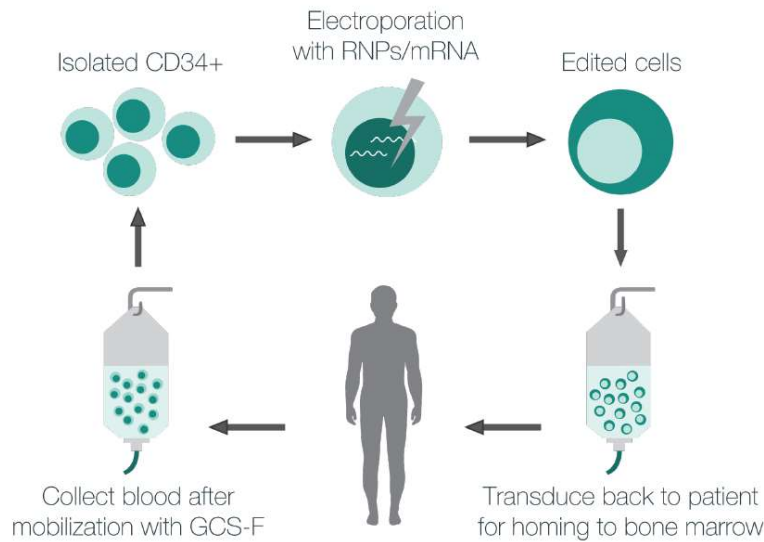
Allele-specific gene editing means **editing selectively targeted abnormal genes** without damaging the other allelic genes.



Emendo will first realize the treatment of many different **dominantly inherited diseases** where there is an abnormality in either of the genes by optimizing their original nuclease to have precision that is high enough to enable safe and effective gene editing. **It will expand the scope of application of genome editing in treatments.**



EmendoBio aims to enter the clinic by the end of 2023 for **ELANE-related severe congenital neutropenia (SCN)** by utilizing Emendo's technology (**OMNI Platform**) to create new genome editing tools.



[Applicable Disease]

■ ELANE (Elastase, Neutrophil Expressed)-related severe congenital neutropenia (SCN)

*Neutropenia stems from a maturation defect of granulocytic series cells in bone marrow. It can result in developing tympanitis, respiratory tract infections, cellulitis, and skin infections repeatedly and occasionally sepsis.

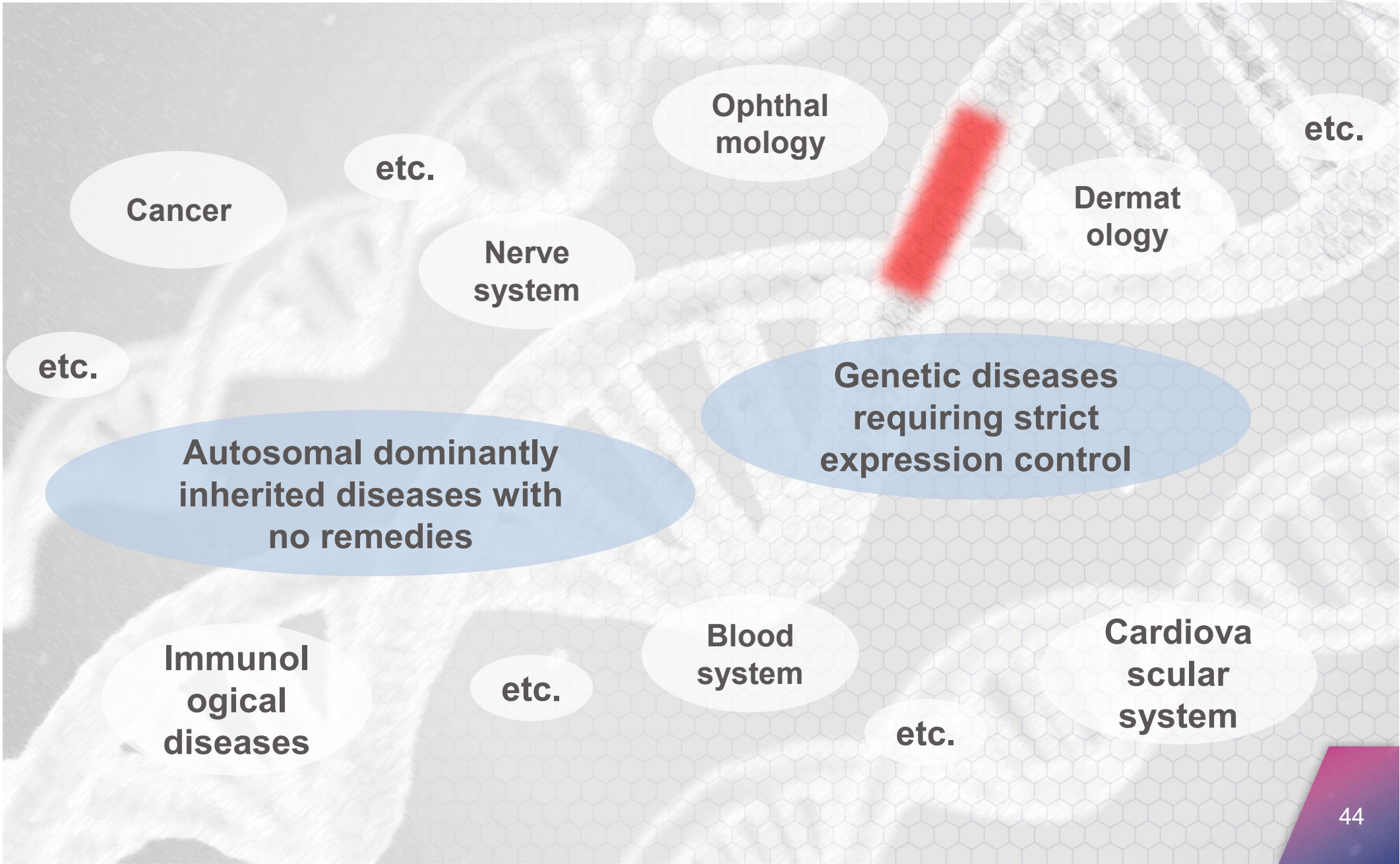
In June 2022, they published their thesis that had been published in the journal of the world' largest group of gene and cellular therapy researchers on their website.

They were able to accurately distinguish and destroy only the abnormal genes with almost identical sequences, without damaging the normal genes, and as a result, the **hematopoietic stem cells were able to differentiate into neutrophils**

David Baram, CEO of EmendoBio, was a guest speaker at the “13th International Collaborative Forum of Human Gene Therapy for Genetic Disease”, held at the University of Tokyo in January



The 13th International Collaborative Forum of Human Gene Therapy for Genetic Disease



Leading Global in Gene Medicine



AnGes's website
<https://www.anges.co.jp/en/>