

AnGes

FY2025 Financial Results Materials



February 2026

- ◆ This document includes forward-looking statements regarding AnGes' current outlook, forecasts, targets, and plans. Forward-looking statements are based on information currently available and on management's judgment. Actual results may differ materially due to various risks and uncertainties. Accordingly, you should not place undue reliance on these forward-looking statements. AnGes has no obligation to update or revise these statements in light of new information, future events, or other findings.
- ◆ The risks and uncertainties described above include changes in the economic environment surrounding AnGes, progress in research and development, regulatory approvals, and revisions to laws and regulations in Japan and abroad.

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Overview of Financial Results for the Fiscal Year Ended December 2025

2

Key Topics for FY2025

- ① Progress of the HGF Gene Therapy Product
- ② Status of the NF- κ B Decoy OligoDNA
- ③ Status of the Tie2 Receptor Agonist (AV-001)

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Additional Topics

- ④ Status of ACRL Testing Operations
- ⑤ EmendoBio's Genome Editing Technology

01

Overview of Financial Results for the Fiscal Year Ended December 2025

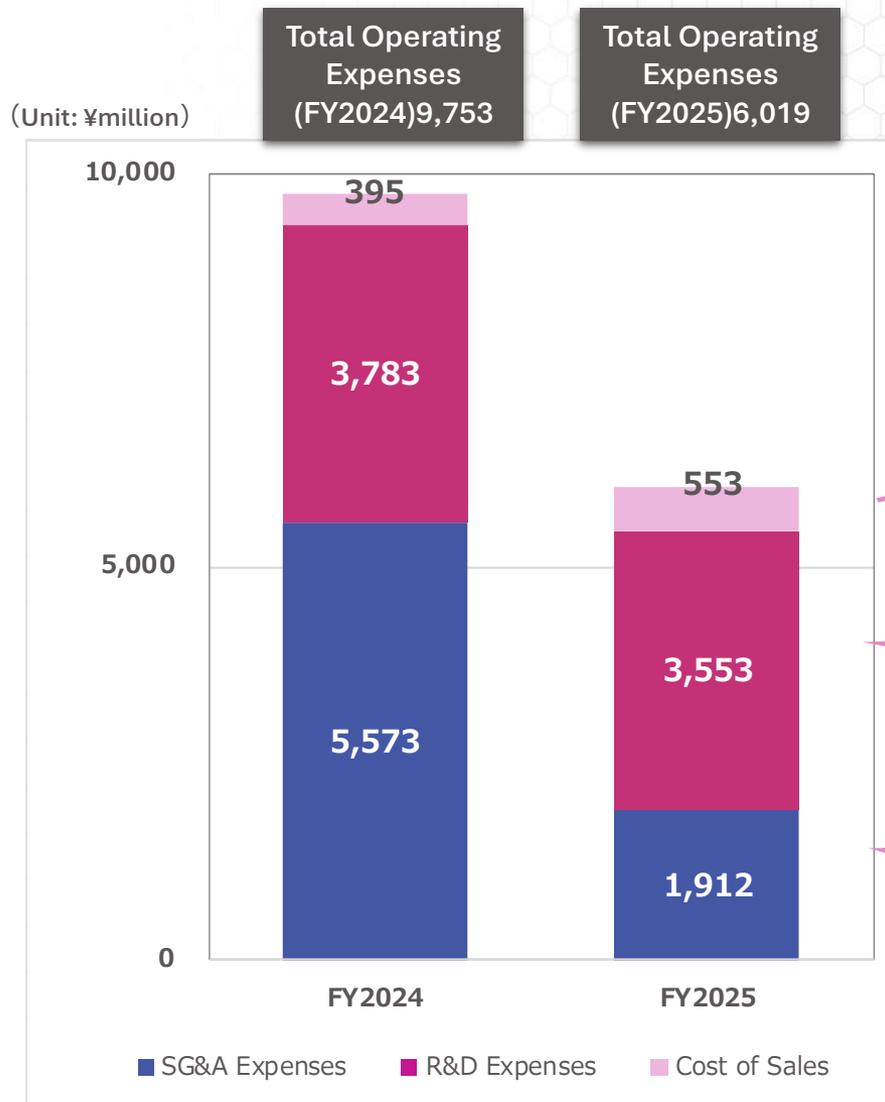
Performance for the Fiscal Year Ended December 2025

(Unit: ¥million)

	Dec. 2024	Dec. 2025	Change	FY2025 Forecast	FY2025 Actual	Variance
Revenue	643	874	230	880	874	-5
Operating Expenses	9,753	6,019	-3,733			
Operating Profit (Loss)	-9,109	-5,145	3,964	-6,270	-5,145	1,124
Non-Operating Income (Expenses)	1,571	-143	-1,714			
Ordinary Profit (Loss)	-7,537	-5,288	2,249	-6,290	-5,288	1,001
Extraordinary Income (Loss)	-20,105	52	20,158			
Net Profit (Loss)	-28,128	-5,123	23,005	-6,320	-5,123	1,196

- The increase in revenue for the period was driven by steady growth in contracted testing services.
- Operating expenses decreased significantly due to the absence of goodwill amortization recorded in the previous year, resulting in an improvement in operating loss.
- Net loss improved substantially as the prior year's special losses from goodwill impairment did not recur.

Breakdown of Operating Expenses



Cost of Sales: ¥553 million
 Increase from prior year: +¥100 million
 • Growth in contracted screening tests: +¥327 million
 • Cost of Zokinvy product: ¥226 million (+¥65 million)

R&D Expenses: ¥3,553 million
 Decrease from prior year: -¥3,613 million
 • Research materials: -¥526 million
 • Outsourcing expenses: +¥325 million

SG & A Expenses: ¥1,912 million
 Decrease from prior year: -¥3,661 million
 • Goodwill amortization: -¥3,322 million
 • EmendoBio-related compensation: -¥201 million
 • EmendoBio-related fees: -¥140 million

Consolidated Balance Sheet Highlights

(Unit: ¥million)

	Dec. 2024	Dec. 2025	Change
Current Assets	3,542	4,386	843
Cash and Deposits	1,707	1,882	174
Non-Current Assets	1,125	1,019	-106
Total Assets	4,668	5,405	737
Liabilities	2,512	2,329	-182
Net Assets	2,156	3,076	919

Current Assets

- Cash and deposits: ¥1,882 million (Increase of ¥174 million from previous year)
Proceeds from Financing: ¥5,939 million
- Raw materials and supplies: ¥308 million
- Advances paid for outsourced manufacturing: ¥292 million

Non-Current Assets

- Non-current assets: ¥1,019 million (Decrease of ¥106 million from previous year)

Liabilities

- Accounts payable: ¥542 million (Increase of ¥235 million from previous year)
- Lease liabilities:
 - Current: -¥109 million
 - Non-current: -¥108 million

Net Assets

- Capital stock: +¥2,972 million
- Capital surplus: +¥2,973 million
- Retained earnings: -¥5,123 million

FY2026 Full-Year Earnings Forecast



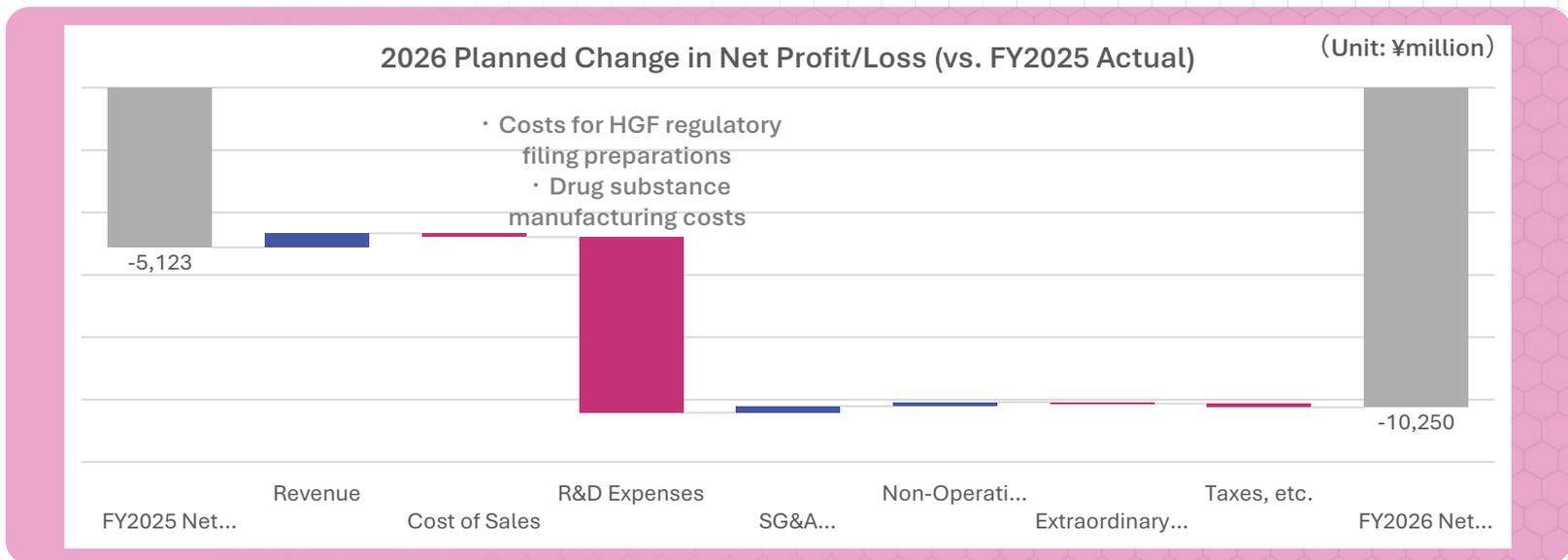
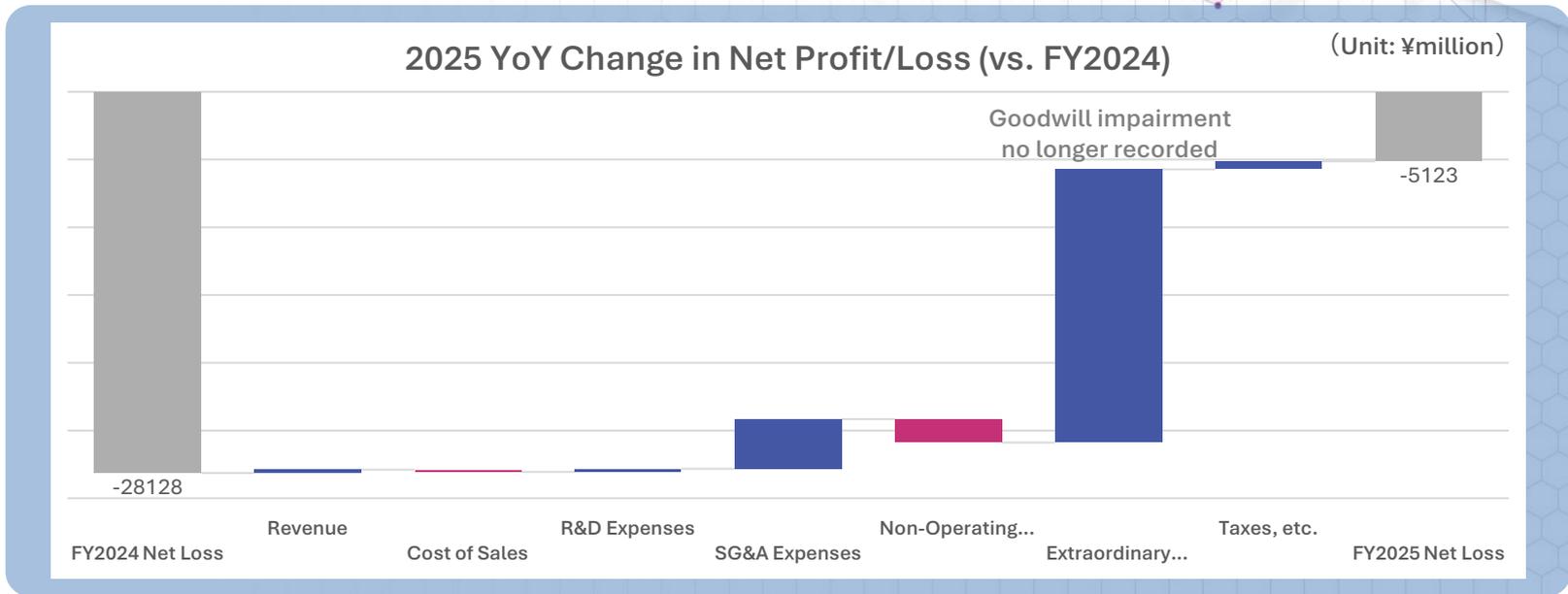
(Unit: ¥million)

	Revenue	Operating Profit (Loss)	Ordinary Profit (Loss)	Net Profit (Loss)
FY2026 Forecast	1,330	-10,230	-10,240	-10,250
FY2025 Actual	874	-5,145	-5,288	-5,123
Year-on-Year Change	456	-5,085	-4,952	-5,127

Key Points of the FY2026 Earnings Forecast

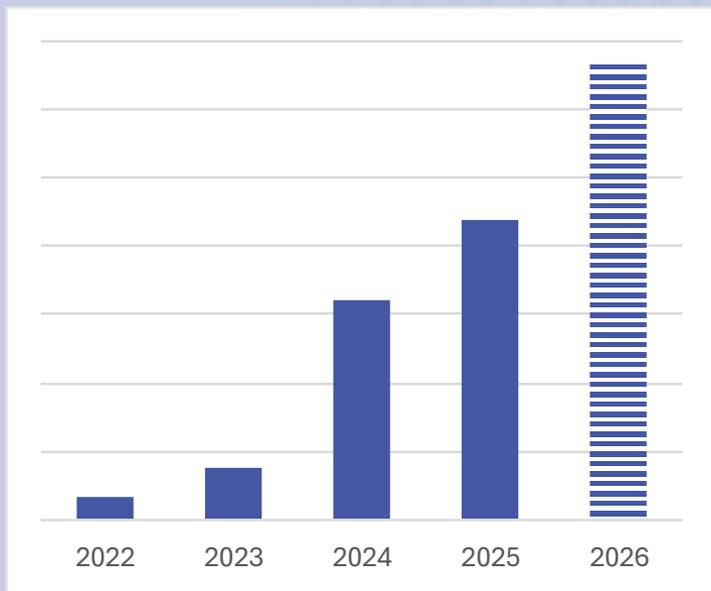
- Sales of Zokinvy are expected to increase.
- Contracted volumes for expanded newborn screening at ACRL are projected to rise slightly.
- Expenses related to preparing the BLA submission for the HGF gene therapy product in the U.S. will increase.
- Costs for manufacturing drug substance for the HGF gene therapy product will be incurred.

Factors Contributing to Changes in Net Profit/Loss



Revenue

(FY2026 figures are forecasts)

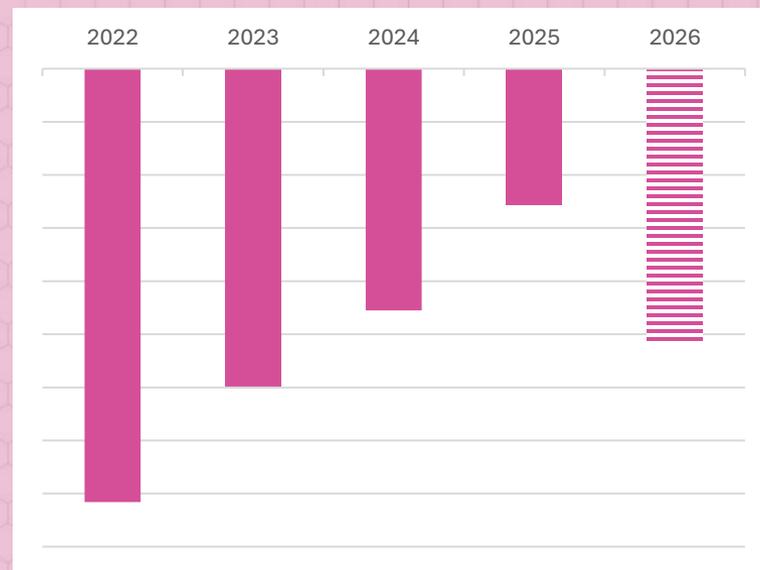


Revenue is increasing

- Sales of Zokinvy are expected to increase.
- Contracted volumes for expanded newborn screening at ACRL continue to grow.
- License revenue associated with EmendoBio contracts will contribute

Operating Profit (Loss)

(FY2026 figures are forecasts)



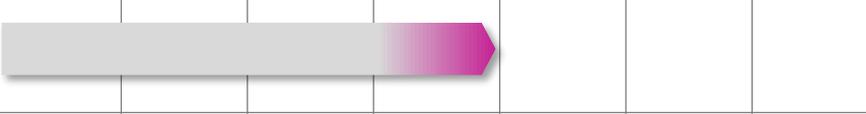
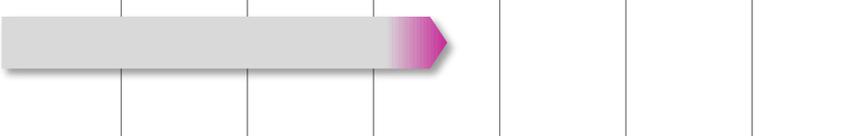
Operating losses will temporarily widen due to U.S. regulatory filing preparations.

- R&D expenses will increase due to costs for the U.S. BLA filing preparations for the HGF gene therapy product and drug substance manufacturing for future commercial supply.

02

Key Topics for FY2025

Status of Our Development Projects

Project	Region	Partner / Licensee	Formulation	Indication	Basic Research	Non-Clinical Studies	Clinical Trials			Regulatory Submission	Approval
							P1	P2	P3		
HGF Gene Therapy Product (Bepmeringene Perplasmid)	Japan	—	Injection	Critical Limb Ischemia (CLI)							
	U S	—	Injection	Comprehensive Limb-Threatening Ischemia (CLTI)							
	Israel / Turkey	Kamada Er-Kim	Injection	Critical Limb Ischemia (CLI)							
NF-κB Decoy OligoDNA	Japan	—	Injection	Chronic Discogenic Low Back Pain							
DNA Vaccine	Australia	—	Injection	Hypertension							
Tie2 Receptor Agonist (AV-001)	U S	Vasomune	Injection	Acute Respiratory Distress Syndrome (ARDS)							

1

Progress of the HGF Gene Therapy Product

2

Status of the NF- κ B Decoy OligoDNA

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Status of the Tie2 Receptor Agonist (AV-001)

1

Progress of the HGF Gene Therapy Product

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Status of the Tie2 Receptor Agonist (AV-001)

Key Progress of the HGF Gene Therapy Product in FY2025

Topic 1

Development Strategy in the United States

Based on the strong results from the U.S. late Phase II clinical trial and subsequent discussions with the FDA, the clinical trial has been deemed complete.

Preparations for the Biologics License Application (BLA) for early approval in the United States are now underway.

Topic 2

Establishment of Post-Approval Drug Substance Manufacturing and Supply Structure

A collaboration has begun with Boehringer Ingelheim BioXcellence™, one of the world's leading pharmaceutical and biopharmaceutical manufacturing companies, to secure the manufacturing and supply framework for commercial production.

Topic 3

Publication of U.S. Phase II Clinical Trial Results

The favorable results of the U.S. late Phase II clinical trial were published in the prestigious journal *Circulation: Cardiovascular Interventions*, issued by the American Heart Association (AHA).

Topic 4

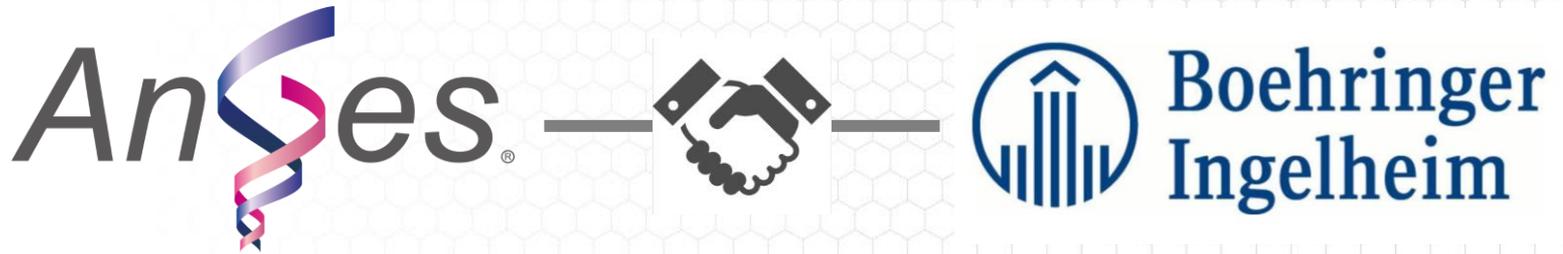
Agreement with the FDA on Regulatory and Clinical Submission Strategy

A Type "B" Clinical Meeting was held with the FDA to discuss the upcoming BLA submission. Agreement was reached with the FDA regarding the regulatory and clinical submission strategy.

Establishing the Post-Approval Drug Substance Manufacturing and Supply Framework



Collaboration initiated with Boehringer Ingelheim BioXcellence™, a leading global pharmaceutical and biopharmaceutical manufacturer



Contract Date

August 20, 2025

Partner

Boehringer Ingelheim BioXcellence™ (One of the world's leading biopharmaceutical CDMOs)

Content

Contract for the development and manufacturing of drug substance for the HGF gene therapy product

Significance

Collaboration with a top-tier global player with a track record of supplying more than 45 commercial products
Ensures reliable CMC data in preparation for FDA approval

Publication of U.S. Clinical Trial Results

Favorable results from the U.S. Phase II clinical trial published in **Circulation: Cardiovascular Interventions**, a journal of the American Heart Association (AHA)

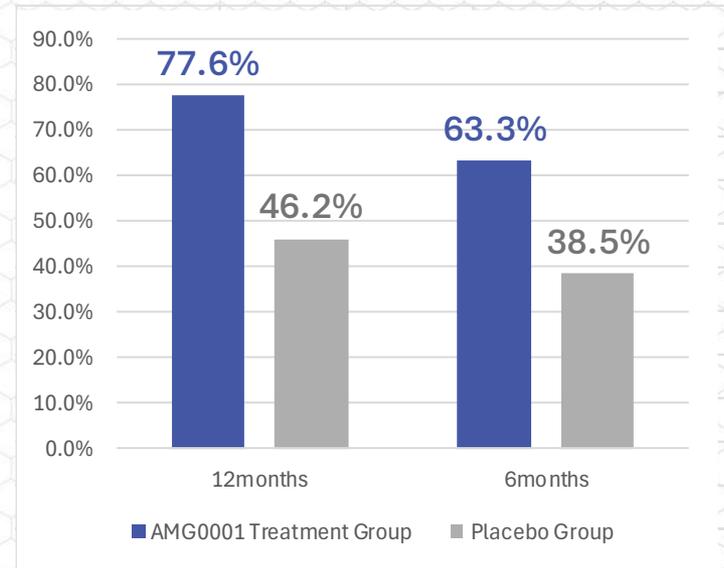
Time to Complete Healing (Median)

Significant reduction in time to ulcer healing in patients with moderate CLTI



Ulcer Healing Rate

High efficacy demonstrated in patients with moderate CLTI



About “Circulation: Cardiovascular Interventions”

A peer-reviewed journal published by the American Heart Association (AHA), featuring clinical and interventional studies focusing on cardiovascular diseases, particularly catheter-based and minimally invasive therapies.

FDA Process for Biologics License Application (BLA)

Based on the strong results from the U.S. late Phase II clinical trial and discussions with the FDA, the clinical trial has been completed and preparations for the Biologics License Application (BLA) are underway.

Standard BLA Submission Process



BLA Submission Process for the HGF Gene Therapy Product



Because the product has been designated as a Breakthrough Therapy, the FDA provides intensive guidance and allows a more efficient review process including Rolling Submission.

Favorable Results from the U.S. Late Phase II Clinical Trial



Clinical trial completed (Phase 3 skipped)

Advancing preparations for the post-approval supply framework

Initiating preparations for the Biologics License Application (BLA)

(Early approval possible under Breakthrough Therapy designation)

Agreement reached with the FDA on the submission strategy at a Type B
Clinical Meeting

**Aiming to begin review under
Rolling Submission during 2026**

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Progress of the HGF Gene Therapy Product

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Status of the NF- κ B Decoy OligoDNA

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Status of the Tie2 Receptor Agonist (AV-001)

NF- κ B Decoy OligoDNA

A research article on the U.S. late Phase I clinical trial in patients with discogenic low back pain was published in *The Spine Journal*, issued by the North American Spine Society (NASS)

In the 10 mg cohort

- **77.4% of patients experienced pain reduction,** and about half reported near-complete pain relief.
- **Improvement in disc height was observed** after treatment in a subset of patients, suggesting potential recovery of the damaged intervertebral disc.

The ongoing domestic Phase II clinical trial aims to **complete enrollment in 2026.**

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Status of the Tie2 Receptor Agonist (AV-001)

Tie2 Receptor Agonist (AV-001)

Developed as a treatment for ARDS,
the product is currently in an early Phase II clinical trial in the United States.

Enrollment of the planned number of patients has been completed,
and additional enrollment is underway to compensate for dropouts.



Targeting completion of enrollment **in the first quarter of 2026**

Designated as Fast Track by the FDA

- More frequent meetings and communication with the FDA
 - Eligibility for accelerated and priority review
- Ability to submit application materials in stages and receive rolling review

Future Development of AV-001

As a new investigator-initiated study, AV-001 will be evaluated for its ability to prevent hemodialysis-induced cognitive decline, reduce cytotoxic brain edema, and preserve white-matter function.

Up to 90% of end-stage renal disease (ESRD) patients undergo hemodialysis.



Hemodialysis can cause symptoms such as confusion, delirium, and long-term cognitive impairment; in patients aged 55 and above, up to 70% develop moderate to severe cognitive dysfunction.

Supported by funding from the Canadian Institutes of Health Research (CIHR), the study aims to stabilize cerebral microvasculature, which is exposed to significant circulatory stress during dialysis.

Agreement signed to expand AV-001's therapeutic target across all applicable disease areas

03

Additional Topics

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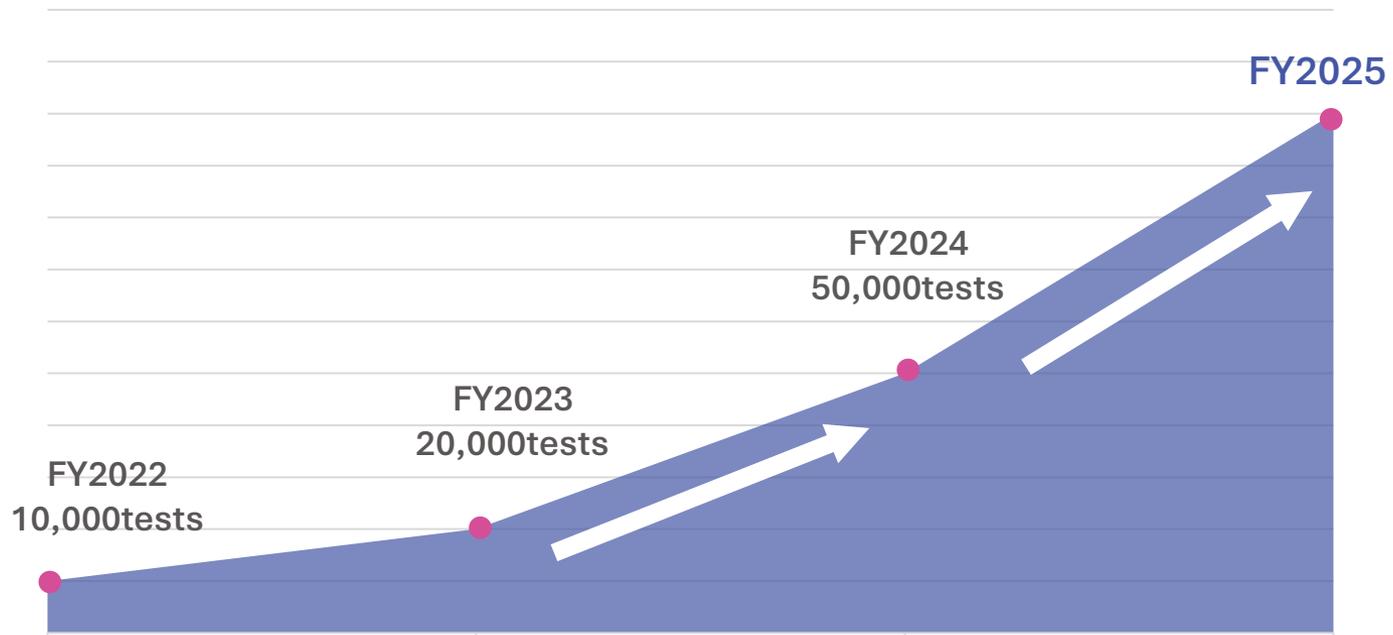
Status of ACRL Testing Operations

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Licensing of EmendoBio's
Genome Editing Technology

Status of Expanded Newborn Screening

The number of expanded newborn screening tests continues to grow approximately 90,000 tests contracted in FY2025



Continuing efforts to expand contracted clients and broaden the range of target diseases

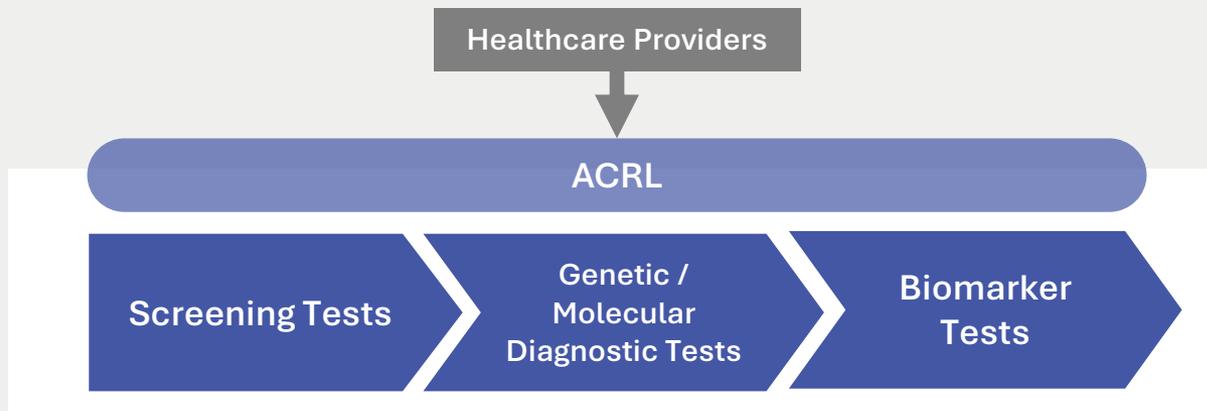
Providing One-Stop Testing for Rare Genetic Disorders



In lysosomal storage diseases, **screening often produces false positives**, placing a significant burden on families and healthcare providers.

To reduce false positives, we have developed and begun offering **a biomarker test as a second-tier screening method.**

ACRL has established a system that provides **a full range of tests related to rare genetic disorders in a single, integrated workflow.**



A false positive refers to a result indicating disease even though the patient does not actually have the condition.

4

Status of ACRL Testing Operations

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Licensing of EmendoBio's
Genome Editing Technology

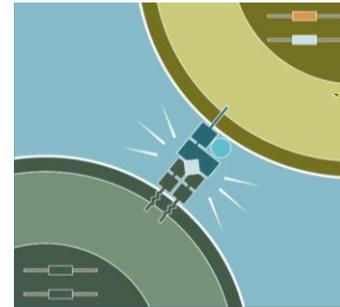
Summary of EmendoBio License Agreement

In 2024, EmendoBio expanded its non-exclusive license agreement with Sweden-based Anocca for the use of the OMNI nuclease, **broadening the scope of permissible applications.**

Engineering Artificial T Cells (TCR-T Cells) that Recognize Cancer-Specific Antigens

Anocca holds a diverse library of TCR receptors specific to various cancers.

Using EmendoBio's OMNI nuclease, the company inserts the genes encoding the appropriate TCR receptors into a patient's T cells to generate TCR-T cells targeting the relevant cancer.



Joint Research with Stanford University

Using EmendoBio's OMNI nuclease, collaborative research has begun with Stanford University to develop a new cancer therapy.

EmendoBio

More precise and efficient genome editing than conventional Cas9 enabled by the OMNI nuclease

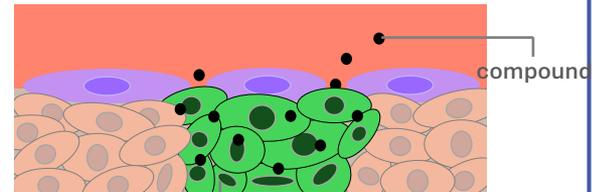


emendo^{bio}



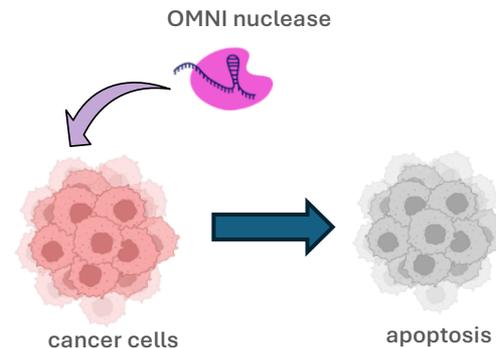
Stanford University

A technology that delivers therapeutics specifically into tumor tissues



Development of a Novel Genome-Editing Cancer Therapy Targeting Breast Cancer

Stanford University has long conducted cutting-edge research in targeted drug-delivery technologies, radiation oncology, and immunotherapy for cancer. By combining Stanford's tumor-targeted delivery technology with EmendoBio's OMNI nuclease genome-editing platform, the collaboration aims to reduce cancer cell resistance to treatment and develop a therapy that selectively eliminates cancer cells.



04

Appendix

HGF Gene Therapy Product

What Is the HGF Gene Therapy Product

What Is Gene Therapy

Gene therapy is a treatment approach in which a specific gene is introduced into the patient's body. The protein expressed from that gene functions within the body to help treat the disease.

What Is HGF

HGF (Hepatocyte Growth Factor) is a substance that promotes the proliferation of hepatocytes. Discovered in Japan in 1984 from liver tissue—an organ with remarkable regenerative capacity—HGF was later found to play essential roles not only in the liver but also in the formation and regeneration of blood vessels, lymphatic vessels, nerves, and other tissues throughout the body.

Discovery of HGF's Ability to Promote Angiogenesis

In 1995, a research team led by Professor Ryuichi Morishita at Osaka University discovered that HGF has the ability to stimulate the formation of new blood vessels. This finding demonstrated that HGF could improve blood flow in ischemic diseases where blood vessels become narrowed or blocked. Based on this unprecedented mechanism—"promoting the formation of new blood vessels"—development began on the HGF gene therapy product, designed to enhance blood flow in ischemic tissues.

*Angiogenesis means creating new blood vessels. As new vessels form, the vascular network is gradually restored.

Five-Year Mortality Rate of Severe Lower-Limb Ischemia

What is Severe Lower-Limb Ischemia

According to Dr. Armstrong of the University of Southern California, the five-year mortality rate among U.S. patients with severe lower-limb ischemia is 57%, making it one of the most life-threatening conditions—second only to lung cancer (80%).

As with cancer treatment, early intervention is critical in managing severe lower-limb ischemia.

A late Phase II clinical trial was conducted in patients with low amputation-risk chronic limb-threatening ischemia (CLTI).

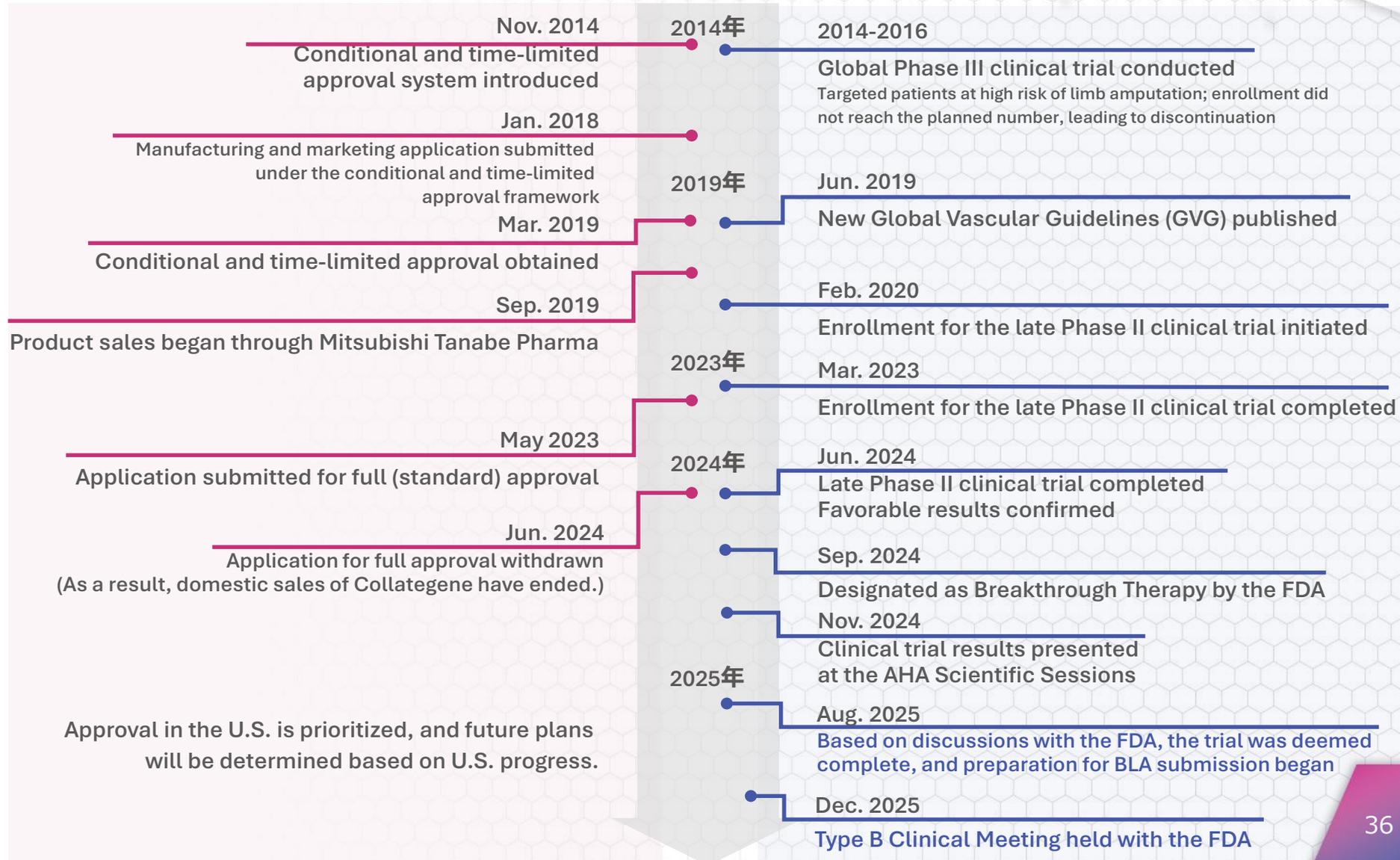
A paper authored by the lead investigator was published in “Circulation: Cardiovascular Interventions”, a journal of the American Heart Association (AHA).

Timeline of the HGF Gene Therapy Product



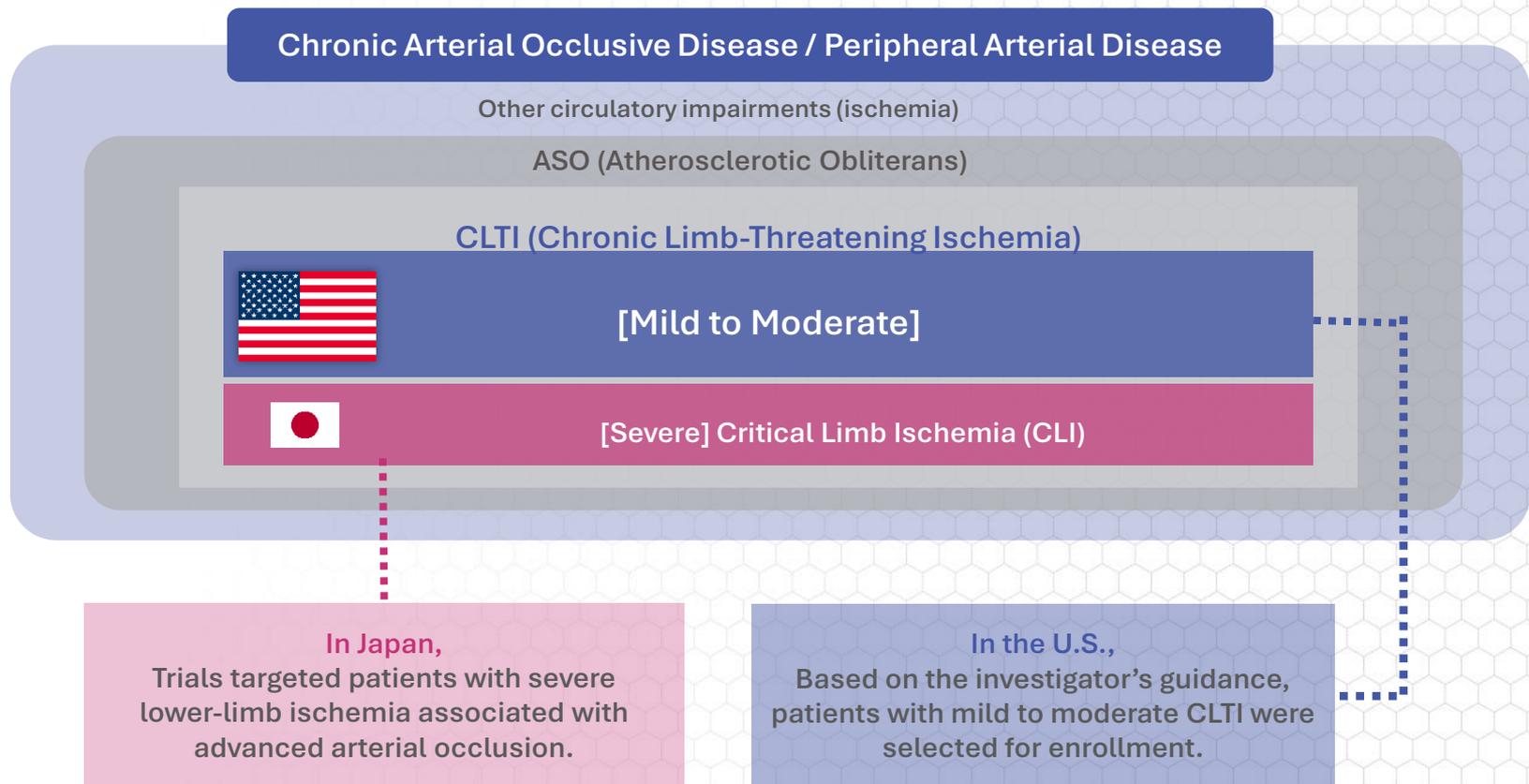
<Japan>

<United States>



Scope of Clinical Trials for HGF in Japan and the United States

Based on the principal investigator's advice that "it is important to treat patients before the condition becomes severe", the U.S. late Phase II clinical trial targeted patients with mild to moderate CLTI.



NF- κ B Decoy OligoDNA

Mechanism of NF-κB Decoy Oligodeoxynucleotide

■ Characteristics as a Nucleic Acid Therapeutic

NF-κB decoy ODN is a short, synthetically manufactured DNA molecule. Unlike traditional small-molecule drugs, it is a next-generation nucleic acid therapeutic that directly controls the expression of genes responsible for disease onset.

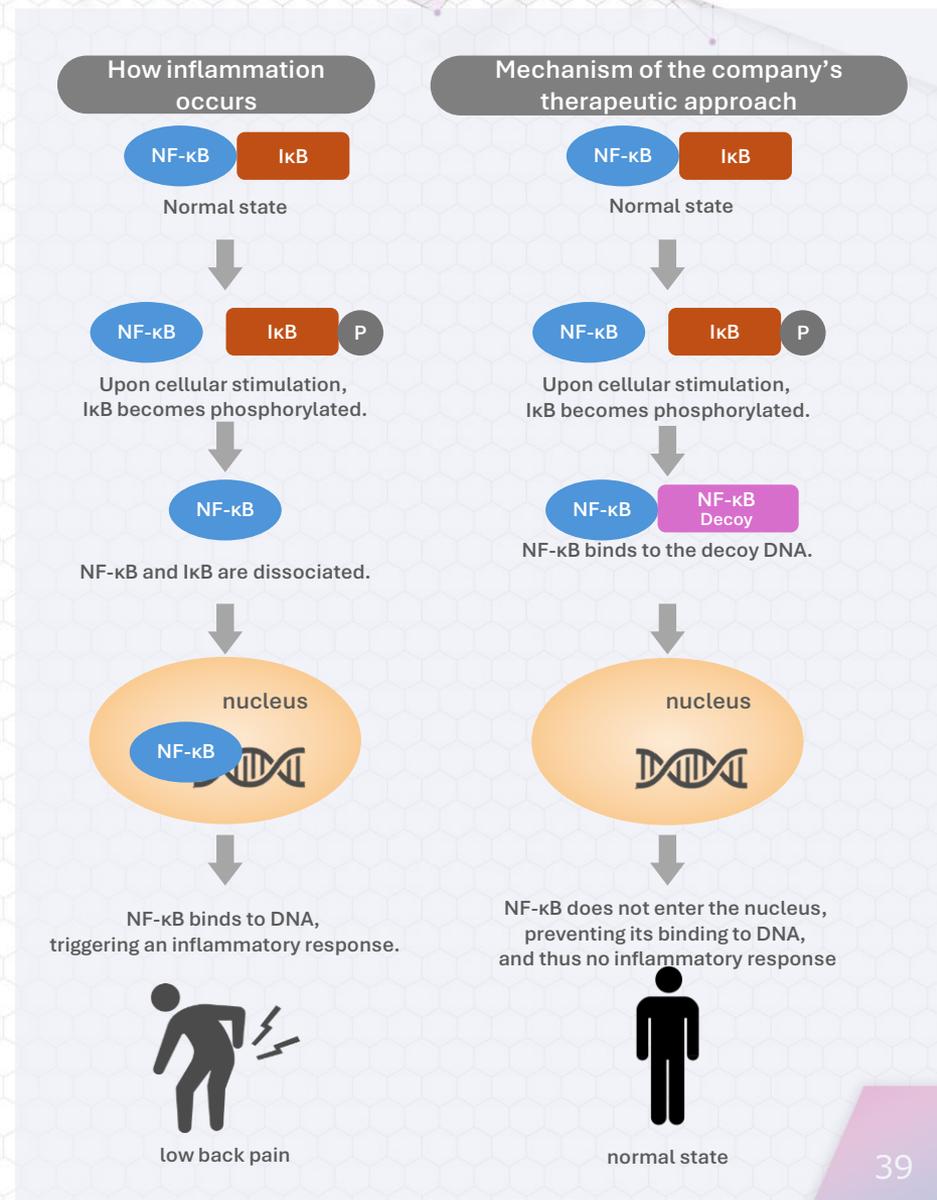
■ Mechanism of Action: A Genetic “Decoy”

Normally, genetic information flows inside the body through the “DNA → RNA → Protein” pathway. NF-κB functions as a molecular switch that turns genes on or off. The decoy (also called a “dummy” DNA) acts by:

- Binding to NF-κB in place of the original genomic DNA
- Blocking the activation of disease-related genes

■ Therapeutic Application in Chronic Inflammatory Diseases

In chronic inflammatory diseases, NF-κB abnormally and continuously binds to DNA and activates the transcription of inflammatory cytokines (e.g., IL-6, TNF-α), sustaining inflammation. NF-κB decoy ODN prevents NF-κB from binding to DNA, thereby fundamentally suppressing immune and inflammatory responses.



Tie2 Receptor Agonist (AV-001)

What Is the Tie2 Receptor Agonist (AV-001)

Tie2 receptor agonist being jointly developed with Vasomune,
a Canadian biopharmaceutical company

Targeting diseases caused by vascular instability and dysfunction,
a Phase I clinical trial began in the United States in 2020,
confirming both safety and tolerability.

About Vasomune

Vasomune Therapeutics, Inc. is a Canadian biopharmaceutical company established in 2014, engaged in the development of next-generation therapeutics that strengthen the body's natural defense against vascular leakage. Focusing on vascular stabilization, Vasomune is developing AV-001 as its lead candidate, aiming to prevent and treat diseases caused by vascular leakage and inflammation. Target indications include viral and bacterial pneumonia, ARDS, sepsis, hemorrhagic shock, acute kidney injury, stroke, vascular dementia, and other related conditions.

About the Tie2 Receptor Agonist

■ What Is the Tie2 Receptor

A receptor protein located on the inner surface of blood vessels (endothelial cells).

- Maintains vascular barrier function
- Strengthens endothelial cell-cell junctions
- Suppresses inflammation and vascular leakage
- Keeps blood vessels stable, shifting them from a “fragile” state to a “healthy” one

■ What Is an Agonist

A molecule that binds to a receptor and activates it, thereby eliciting its biological effect.

What is ARDS

ARDS (Acute Respiratory Distress Syndrome)

ARDS is a severe respiratory failure caused by various factors, characterized by sudden onset of breathing difficulty, reduced blood oxygen levels, and widespread inflammation and leakage in the lungs.

Symptoms: "Breathing becomes difficult"

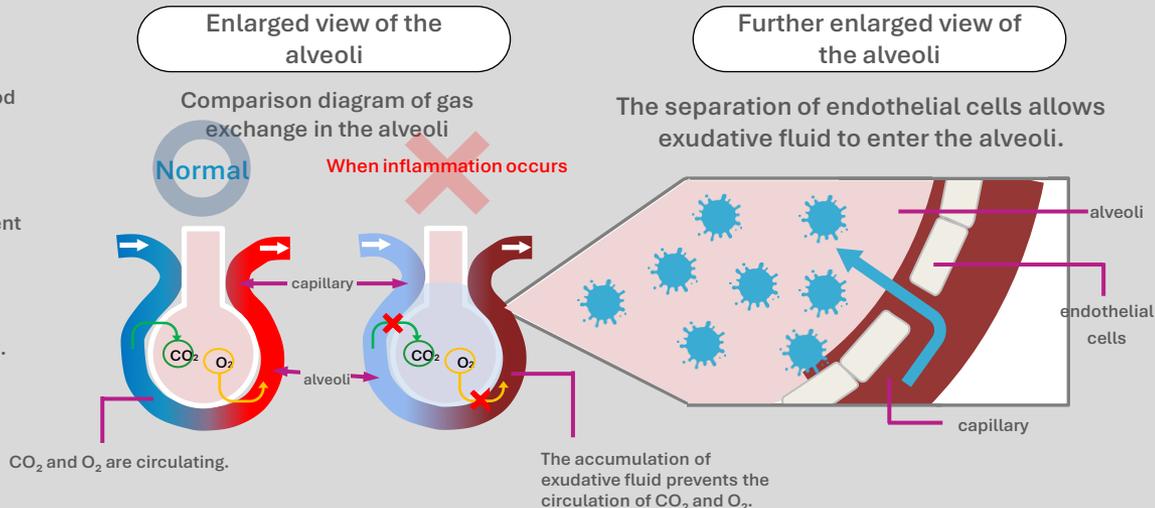
Due to inflammation, fluid leaks into the alveoli, preventing sufficient oxygen from entering the body. Chest X-rays often show hazy, "white-out" appearances due to this fluid accumulation.

Current Standard Treatments (Supportive Care)

Treatment is aimed at supporting breathing while the lungs recover.

Typical approaches include:

- Mechanical ventilation (respirator support)
- Fluid management
- Prone positioning therapy

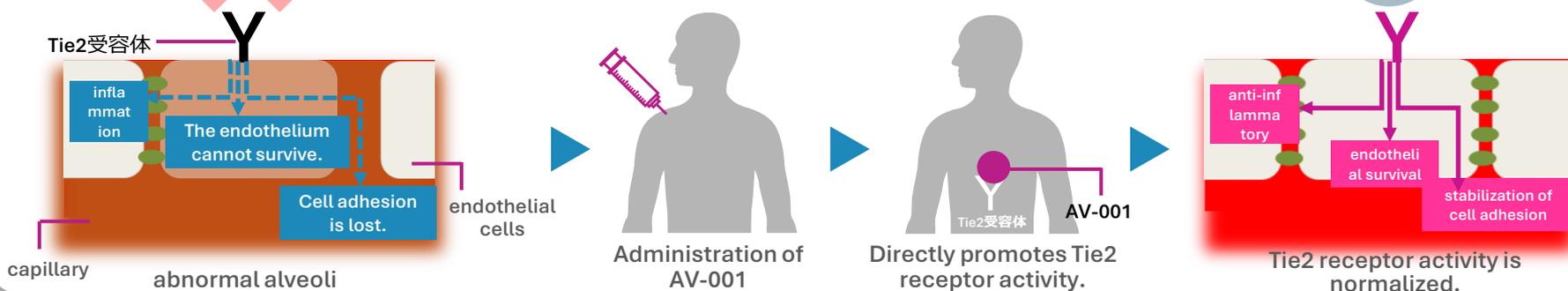


Mechanism of AV-001 (Maintenance and Restoration of Vascular Physiological Function)

When Tie2 receptor function is suppressed, endothelial cells separate, allowing exudate to enter the alveoli.

By administering AV-001, Tie2 receptor activity is returned to normal.

With AV-001, Tie2 receptor activity is normalized.



Zokinvy

About Zokinvy

Zokinvy is a treatment for Hutchinson–Gilford Progeria Syndrome (HGPS) and processing-deficient progeroid laminopathies (PDPL).

Target Diseases

Pediatric Progeroid Syndromes: “HGPS” and “PDPL”

Early-onset progeroid syndromes are conditions in which the signs of aging appear much earlier than normal due to abnormalities in the aging mechanism, affecting the entire body. Among these, HGPS is characterized by symptoms resembling rapid aging from early childhood. The average life expectancy of patients with HGPS is reported to be approximately 14.5 years.

Efficacy

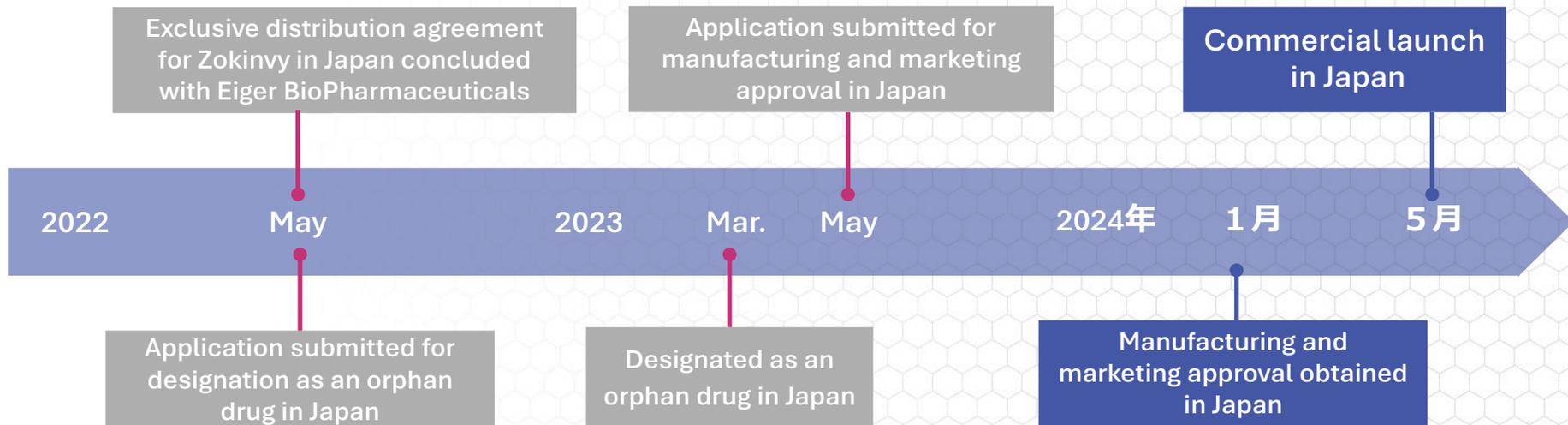
In patients with Hutchinson–Gilford Progeria Syndrome (HGPS), studies have shown that Zokinvy can: Reduce mortality by 72%, and Extend average lifespan by approximately 2.4 years.

Safety

Many patients with HGPS have been receiving Zokinvy for over 10 years. Reported adverse effects include nausea, diarrhea, and vomiting, but most cases are mild to moderate.

About Zokinvy

Launch Date: May 27, 2024



Zokinvy (Lonafarnib)



Pricing

¥91,796.40 per Zokinvy 50 mg capsule (1 capsule)
 ¥136,544.00 per Zokinvy 75 mg capsule (1 capsule)

Indications and Clinical Use

Hutchinson–Gilford Progeria Syndrome (HGPS) and Progeroid Laminopathies with defective processing of Lamin A

Dosage and Administration

Initial dose: 115 mg/m² of body surface area, taken orally twice daily with morning and evening meals
 After 4 months, increase to 150 mg/m², taken orally twice daily with meals
 Dose adjustment as needed based on patient condition

AnGes Clinical Research Laboratory

What is the AnGes Clinical Research Laboratory (ACRL)

A public health testing facility specializing in rare genetic disease testing.

AnGes Clinical Research Laboratory

Commissioned for Expanded Newborn Screening Services

FY2025:
90,000 tests



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FY2024:
50,000 tests

Going forward, ACRL will work to expand the number of commissioned tests and broaden the range of diseases included in the screening panel.

Testing for Newborns

Newborn Mass Screening (Public Mass Screening)

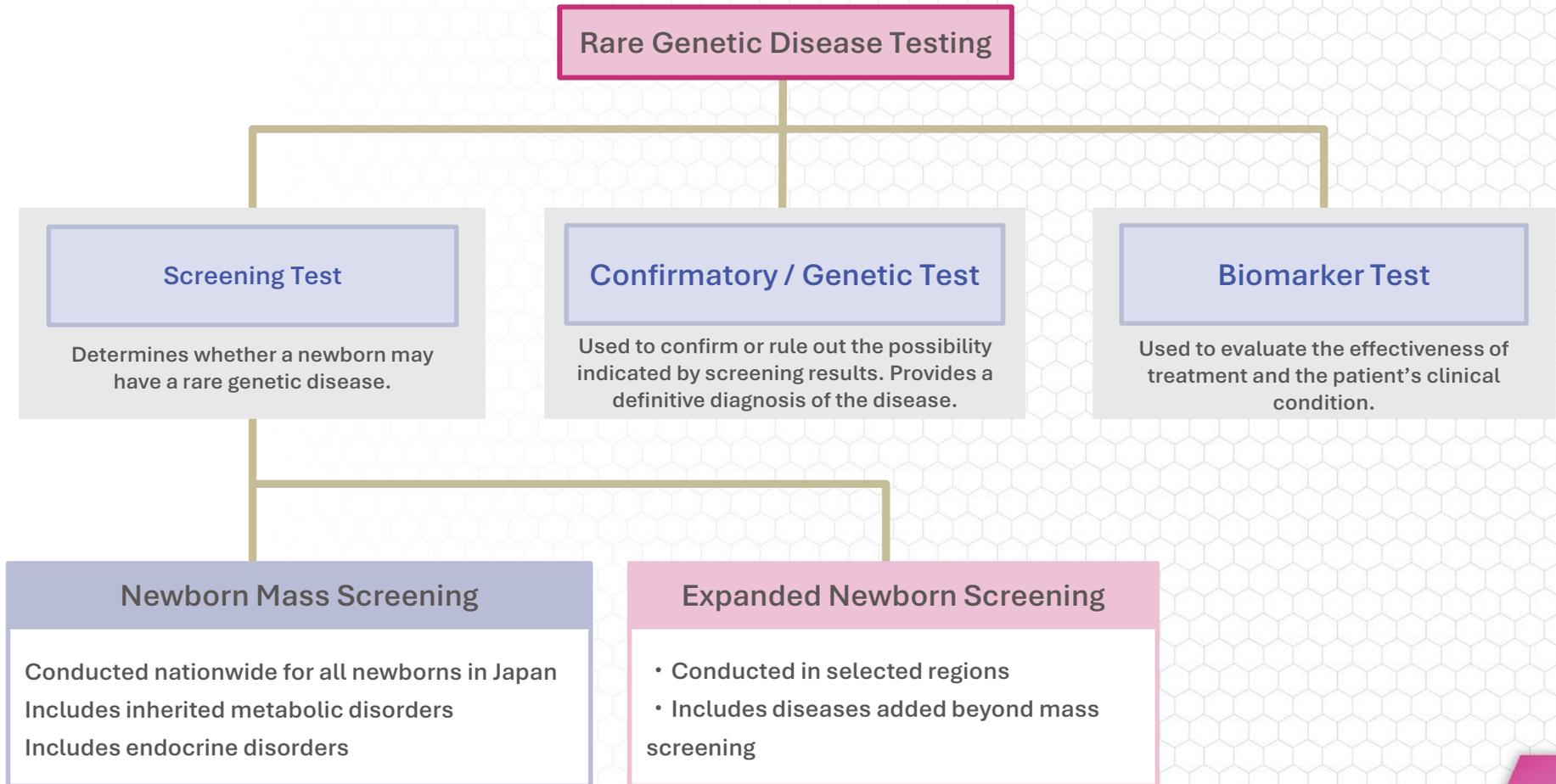
Conducted nationwide for all newborns in Japan
Includes inherited metabolic disorders
Includes endocrine disorders

Expanded Newborn Screening

- Conducted in selected regions
- Includes diseases added beyond mass screening

About Testing for Rare Genetic Diseases

Testing for rare genetic diseases includes
“Screening tests,” “Genetic tests,” and “Biomarker tests.”

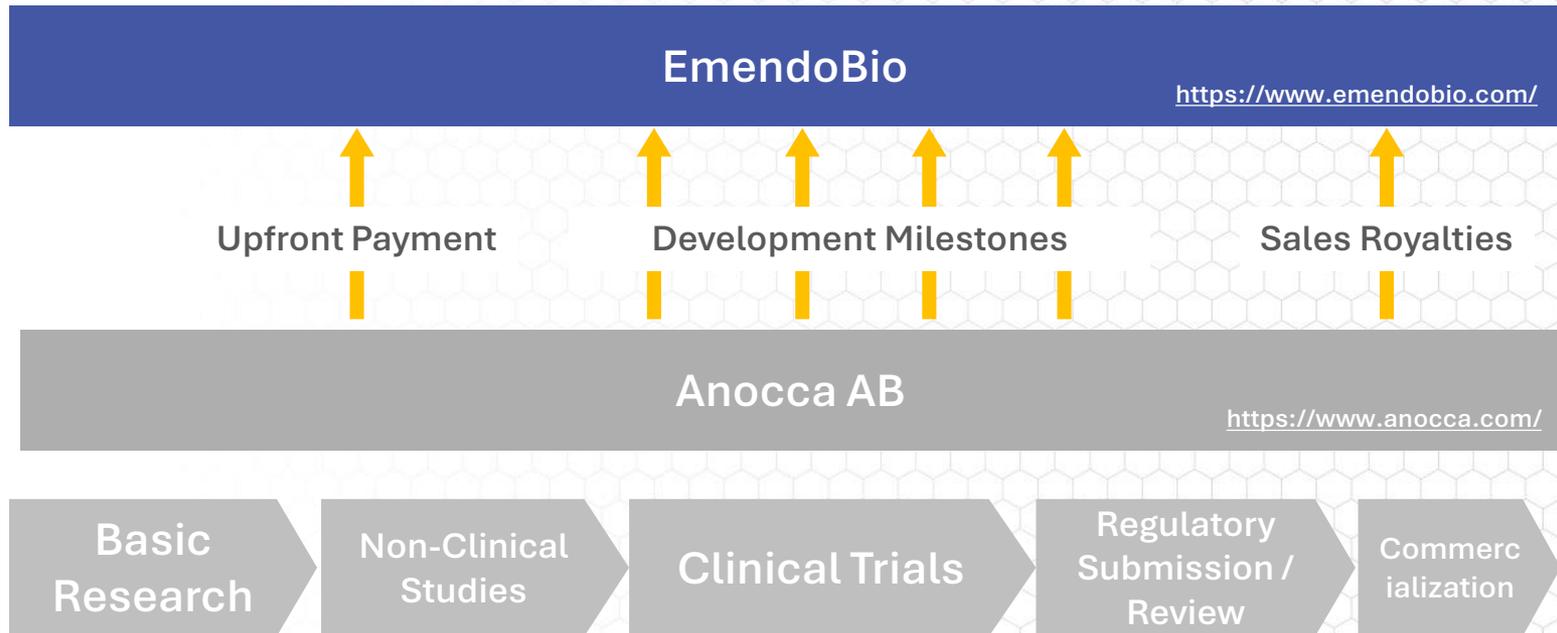


EmendoBio

Summary of the EmendoBio License Agreement

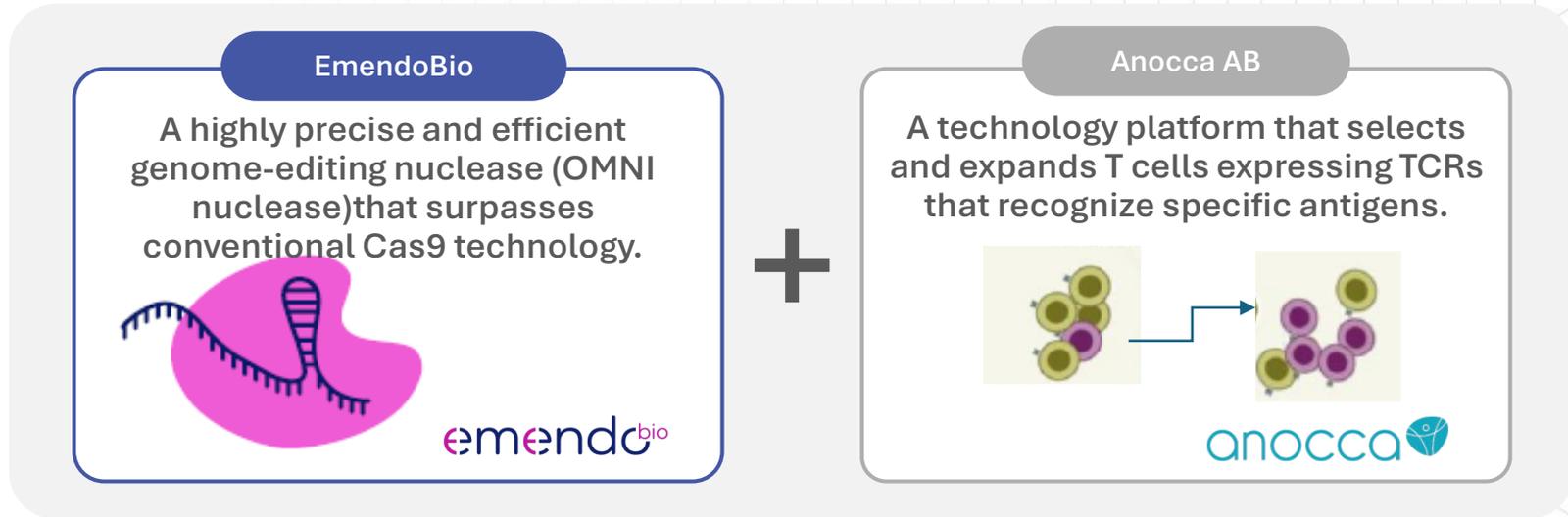
March 14, 2024

EmendoBio entered into a license agreement with Anocca AB of Sweden (Granting non-exclusive rights to use EmendoBio's OMNI nuclease for genome editing)



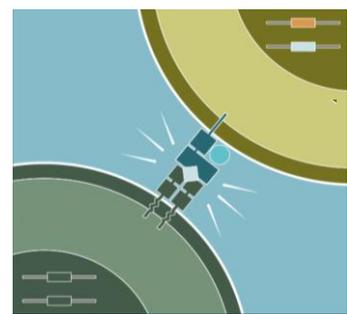
TCR-T Cell Therapy

Anocca is developing a TCR-T cell therapy targeting KRAS protein mutations found in solid tumors, using the OMNI nuclease developed by EmendoBio for highly precise genome editing.



Creating TCR-T Cells that Recognize Cancer-Specific Antigens

Anocca possesses a library of TCRs specific to various solid tumors. By combining these TCRs with EmendoBio's OMNI nuclease, TCR-T cells are engineered to express the TCRs needed to target cancer cells.



About Immunotherapy

Immunotherapy is a treatment in which a patient’s own immune cells—specifically T cells—are collected, enhanced to fight cancer, and then returned to the body.



Since the patient’s own immune cells are used, **there is no concern that healthy tissues will be attacked.**

Blood Cancers

Cancers that arise from abnormalities in hematopoietic tissues
(e.g., leukemia, malignant lymphoma, multiple myeloma)



CAR-T Cell Therapy

CAR-T cell therapy introduces a genetically engineered chimeric antigen receptor (CAR) into the patient’s T cells. CAR-T therapy has achieved major breakthroughs in hematologic malignancies; however, because CARs recognize only cell-surface antigens, applying CAR-T to solid tumors remains challenging.

Solid Tumors

Cancers that form solid masses of cancer cells
(e.g., pancreatic cancer, lung cancer, colorectal cancer, esophageal cancer)



Anocca AB

TCR-T Cell Therapy

EmendoBio

TCR-T cell therapy, on the other hand, uses T-cell receptors (TCRs) that can recognize intracellular tumor-derived antigens presented via MHC molecules. This enables targeting of a much broader range of antigens, making TCR-T therapy a promising approach for treating solid tumors.

Harnessing gene power to make treatment accessible to all



AnGes Website
<https://www.anges.co.jp/en>