AnGes

FY2023 Financial Results Materials

— Leading Global in Gene Medicine —

February 2024

◆ **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.

1 Summary of Financial Results for FY2023

2 Topics

①Zokinvy
②HGF Gene Therapy Product
③NF-κB decoy oligonucleotide DNA
④Tie2 Receptor Agonist
⑤ACRL

3 Other developed products,
Collaboration with partner companies

01

Summary of Financial Results for FY2023

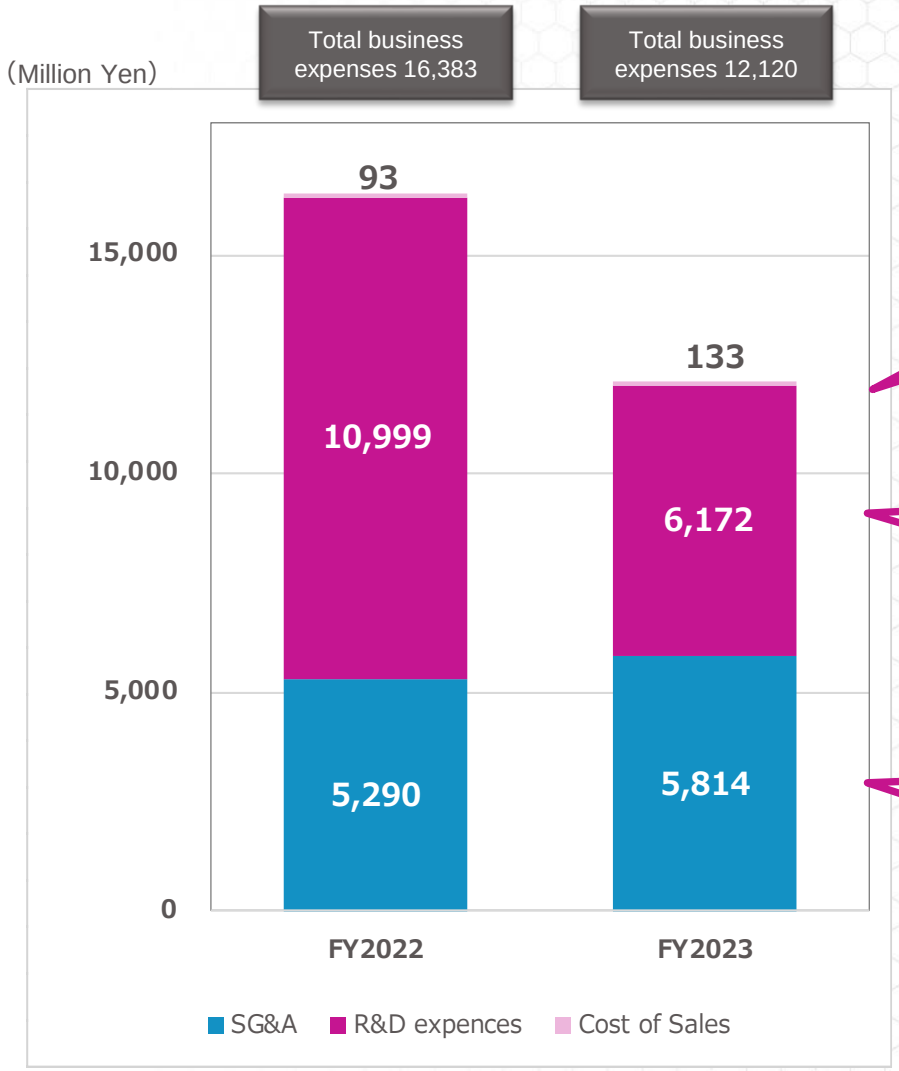
Highlights of Consolidated Results for FY2023

(Million Yen)

	Y2022	FY2023	Increase /decrease	FY2023 Earning Forecast	FY2023 Result	Increase /decrease
Revenues	67	**152**	85	190	**152**	-37
Business Expenses	16,383	**12,120**	-4,263		**12,120**	
Operating Profit	-16,316	**-11,967**	4,349	-13,500	**-11,967**	1,532
Non-operating income/expenses	1,706	**6,316**	4,609		**6,316**	
Ordinary Profit	-14,610	**-5,651**	8,958	-7,500	**-5,651**	1,848
Extraordinary income/losses	-106	**-1,820**	-1,713		**-1,820**	
Profit	-14,714	**-7,437**	7,277	-7,500	**-7,437**	62

- **Revenues in FY2023 results were generally on schedule for Collategene sales, expanded newborn screening tests increased from the previous year, but did not reach the plan.**
- **R&D expenses were reduced due to the discontinuation of R&D for a new corona vaccine, etc.**
- **Loss on revaluation of marketable securities and expenses related to Emendo's business reorganization were recorded as extraordinary losses.**

Details of Business Expenses



Cost of Sales：133

（YoY +39 +42.5%）
Increase in depreciation due to introduction of new equipment in "Contracted Inspections"

R&D expenses： 6,172

（YoY △4,826、△43.9%）
① Research material expenses 729（△1,228）
② Outsourcing expenses 1,995（△3,910）
Decrease in research material costs and clinical trial-related costs for Covid-19

SG&A： 5,814

（YoY +523、+9.9%）
①Fees and commissions 1,213（+358）
Increase in Emendo-related consulting expenses
③ Goodwill 3,081（+197）
Increase in amortization expense due to yen depreciation (to value dollar-denominated "goodwill" in yen)

Consolidated Balance Sheet Highlights

(Million Yen)

	Dec. 31, 2022	**Dec. 31, 2023**	Increase /Decrease
Current assets	12,896	**5,921**	-6,975
Cash and deposits	11,035	**4,160**	-6,874
Non-current assets	25,924	**22,971**	-2,952
Goodwill	23,254	**21,746**	-1,508
Total assets	38,820	**28,892**	-9,928
Liabilities	8,395	**2,789**	-5,605
Net assets	30,425	**26,103**	-4,322

Current assets

■Cash and Deposits 4,160（△6,874）
2,055 in financing, but decreased due to project expenditures
■Raw materials and supplies 1,468(+463)
Increased due to production of Collategene API

Non-current assets

■Goodwill 21,746（△1,508）
■Right-of-use assets of Emendo's building 267（△1,050）
Review of accounting standards for business structure improvement

Liabilities

■advance received 637（△5,126）
Unrecognized grants are recorded as grant income
■Lease obligations 362（△793）

Net assets

■Capital stock/capital surplus as a result of fundraising +1,032
■Retained earnings due to loss for the year △7,437
■Appropriated to cover losses
Capital △1,125 Capital reserve △15,076
Retained earnings brought forward +16,202

Earning Forecast for FY2024

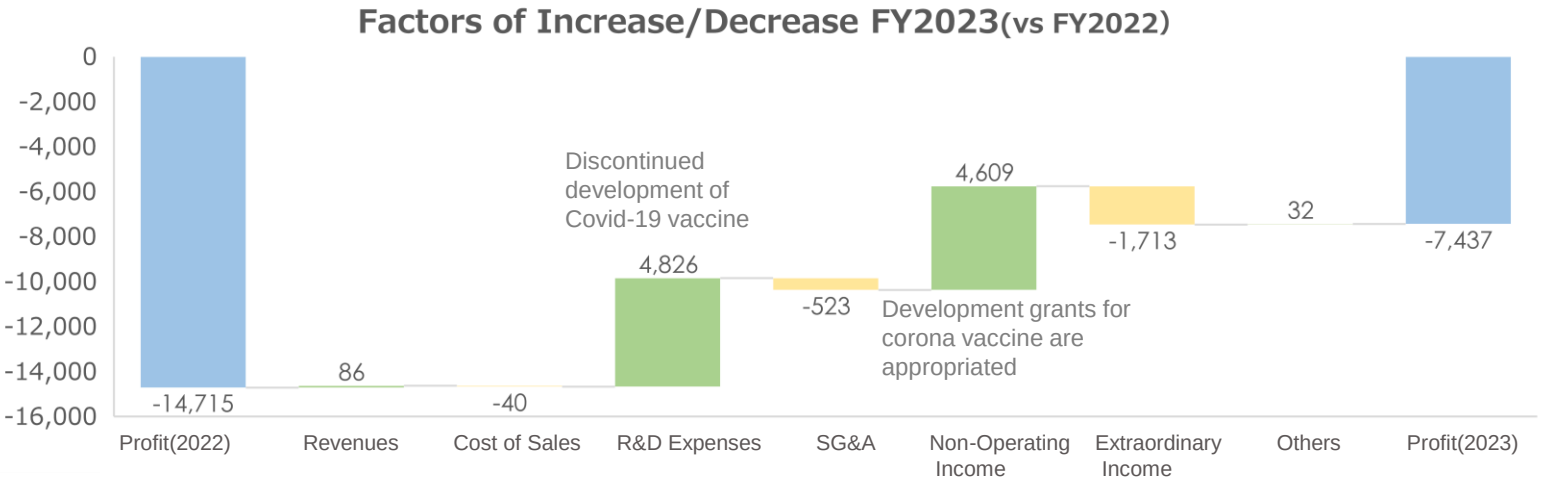
(Million Yen)

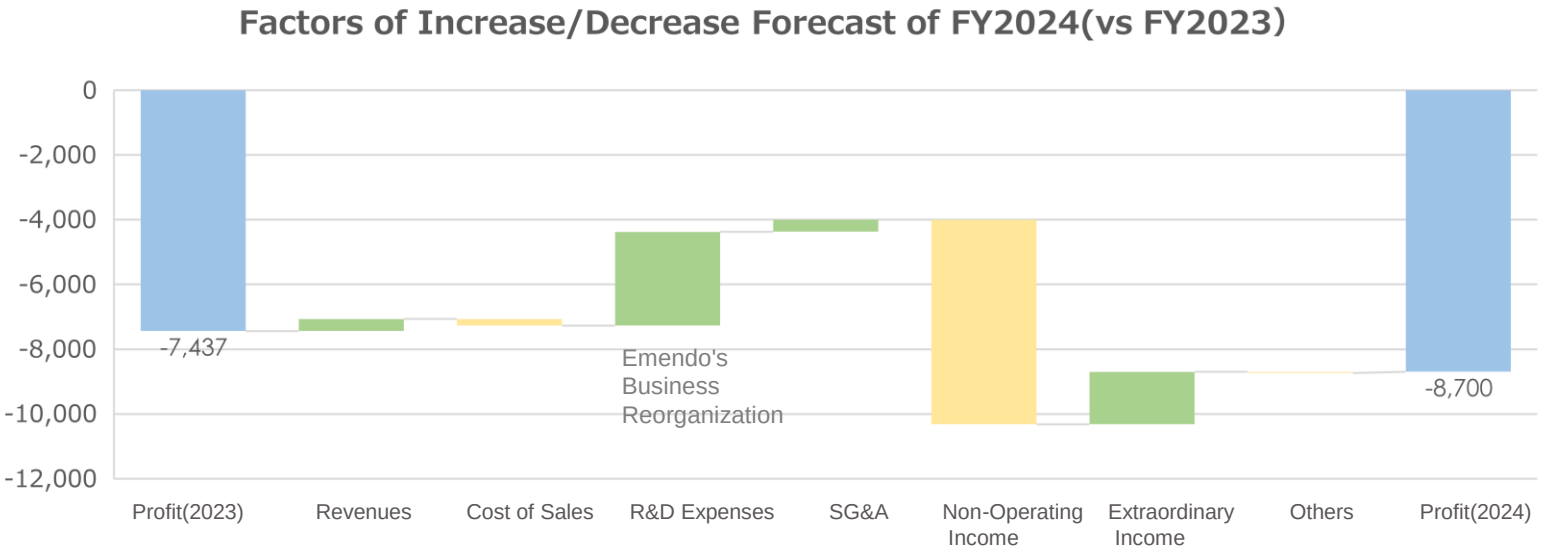
	Business Revenues	Operating Profit	Ordinary Profit	Profit
FY2024 full-year plan	**530**	**-8,500**	**-8,500**	**-8,700**
FY2023 full-year results	152	-11,967	-5,651	-7,437
Increase / decrease	378	3,467	-2,849	-1,263

Key Points of Full-Year Earnings Forecast FY2024

- Start of sales of Zokinvy following its approval for production and marketing
- Increase in the number of expanded newborn screening contracts at ACRL
- Reduction of R&D expenses due to restructuring of Emendo's business
- Loss of subsidy income recorded in FY2023.

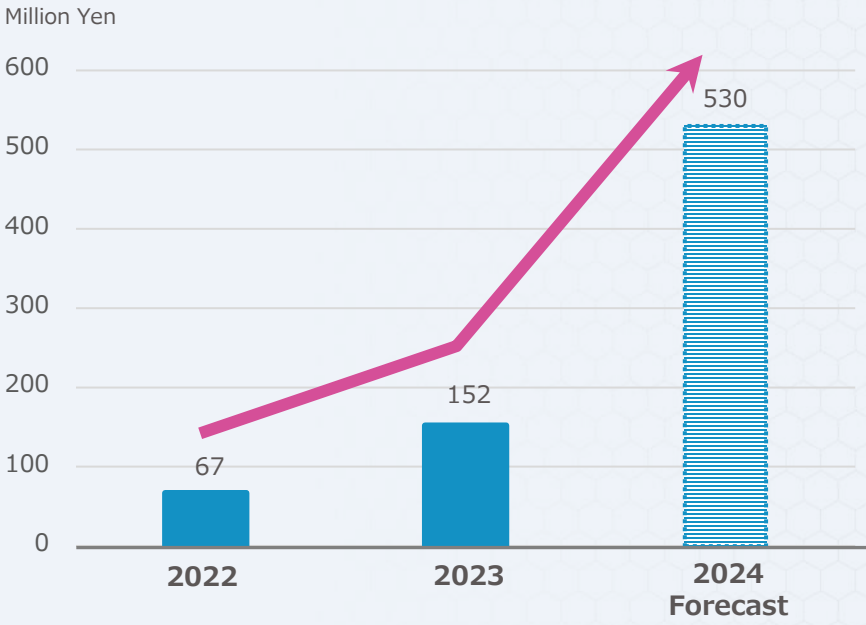
Factors of Increase/Decrease in Net Income (Loss)





Financial Results

Revenues



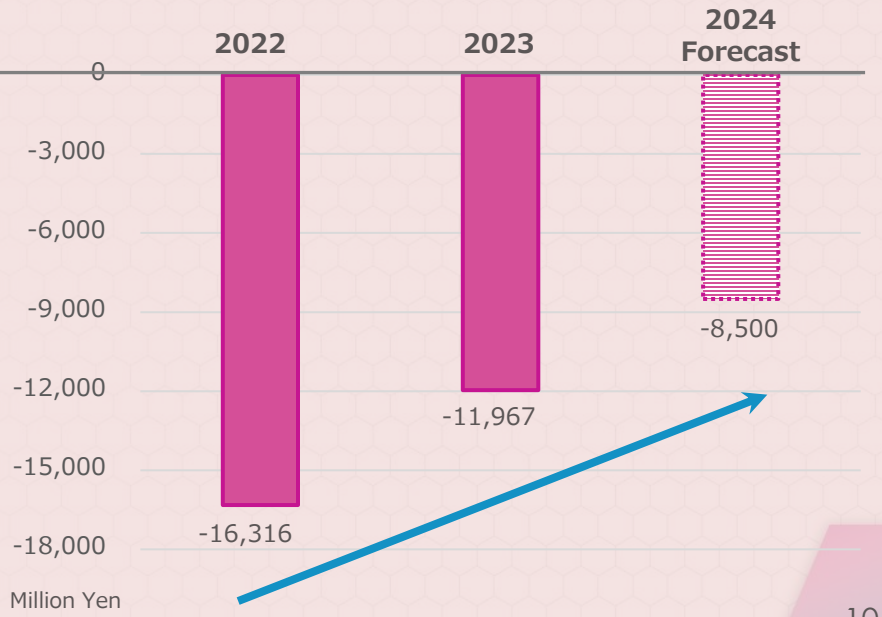
・In 2023, we will achieve more than doubling of business revenues from the previous year
・In 2024, sales of Zokinvy will begin following its marketing approval and the number of expanded newborn screening contracts at ACRL will increase.

Revenues increased

Operating Income

・Reduced R&D expenses by suspending R&D of Covid-19 vaccine, etc.
・Reduction of R&D expenses due to reorganization of Emendo

Operating income improved



02

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	Application

■ 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)			
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 lumber back pain			Completed				
DNA vaccine	Australia	–	Injectable	Hypertension			Completed				
DNA vaccine	US	–	Intranasal formulation	COVID-19 / ADRS	On going						
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					Approved	

FY2023 Topics

1	Received approval to manufacture and market Zokinvy in Japan for the treatment of premature aging
2	HGF gene therapy products main approval filed
3	Phase II clinical trial of NF-κB decoy oligo DNA in Japan
4	Phase II Clinical Trial of Tie2 Receptor Agonist in the U.S.
5	Testing services at ACRL

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Our Business Objectives

Our goal is to contribute to the improvement of people's lives and the standard of medical care through the development of innovative drugs for **disease areas for which there is no cure**, **intractable diseases**, and **rare diseases**, etc. To this end, we aim to deliver innovative drugs that are internationally accepted to patients as quickly as possible.

Introduced Zokinvy, currently being sold in the U.S., to Japan

About Zokinvy, a drug for the treatment of Progeria

About Zokinvy

Zokinvy is a drug for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS) and processing-deficient progeroid laminopathy (PL) marketed by Eiger BioPharamaceuticals Inc. in the United States.

This product will be first approved by the U.S. FDA in November 2020 for the treatment of HGPS mortality risk reduction and processing failure PL, followed by approval in the European Union and the United Kingdom.

AnGes signed an exclusive distribution agreement with Eiger in Japan in May 2022, and Zokinvy is designated as an orphan drug* by the Ministry of Health, Labour and Welfare in March 2023.

※ Orphan drugs are drugs for rare 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 system for orphan drugs, and those who obtain orphan drug designation are entitled to benefits and support measures such as priority review and, if approved, a 10-year priority marketing period.

Target diseases/efficacy and safety of Zokinvy

Target diseases

"HGPS" and "processing failure PL", known as **Progeria Infantilis**. Assumption is that the number of patients to be used will start with a few.

※What is Progeria Infantilis?
Progeria is a general term for a disease in which the signs of aging occur earlier than the actual age of the patient and are seen throughout the body. The average age of HGPS is reported to be 14.5 years.

Efficacy and safety of Zokinvy

◆**Efficacy**

Data show a 72% reduction in mortality and an increase in mean survival of about 4 years in patients with HGPS

◆**Safety**

Many HGPS patients have been on Zokinvi treatment for more than 10 years, and the most common side effects reported are vomiting, diarrhea, and nausea, most of which are mild or moderate

Rare Disease Initiatives and Zokinvy

Received approval to manufacture and market ZOKINVI in Japan for the treatment of Progeria on January 18, 2024.

Proprietary OMNI Platform to create a number of OMNI nucleases that can avoid off-target effectsAiming to enter clinical trials for ELANE-related severe congenital neutropenia

EmendoBio, which develops genome-editing therapies, becomes a subsidiary

Screening test commissioned to determine the likelihood of rare genetic disorders in newborns

Opened ACRL, a sanitary laboratory with the main purpose of testing for rare genetic diseases

2008 ～ 2019 | **2020** | **2021** | **2022** | **2023** | **2024**

Naglazyme" for the treatment of Mucopolysaccharidosis Type VI

Business transferred to BioMarine's Japanese subsidiary in 2019

Exclusive distribution agreement signed with Eiger for Zokinvy in Japan

Submitted an application for manufacturing and marketing approval of "Zokinvy" in Japan

厚生労働省より希少疾病医薬品の指定を受ける

Received approval to manufacture and market "Zokinvy" in Japan

In the future, we plan to study diseases that can be treated by the mechanism by which Zokinvy works

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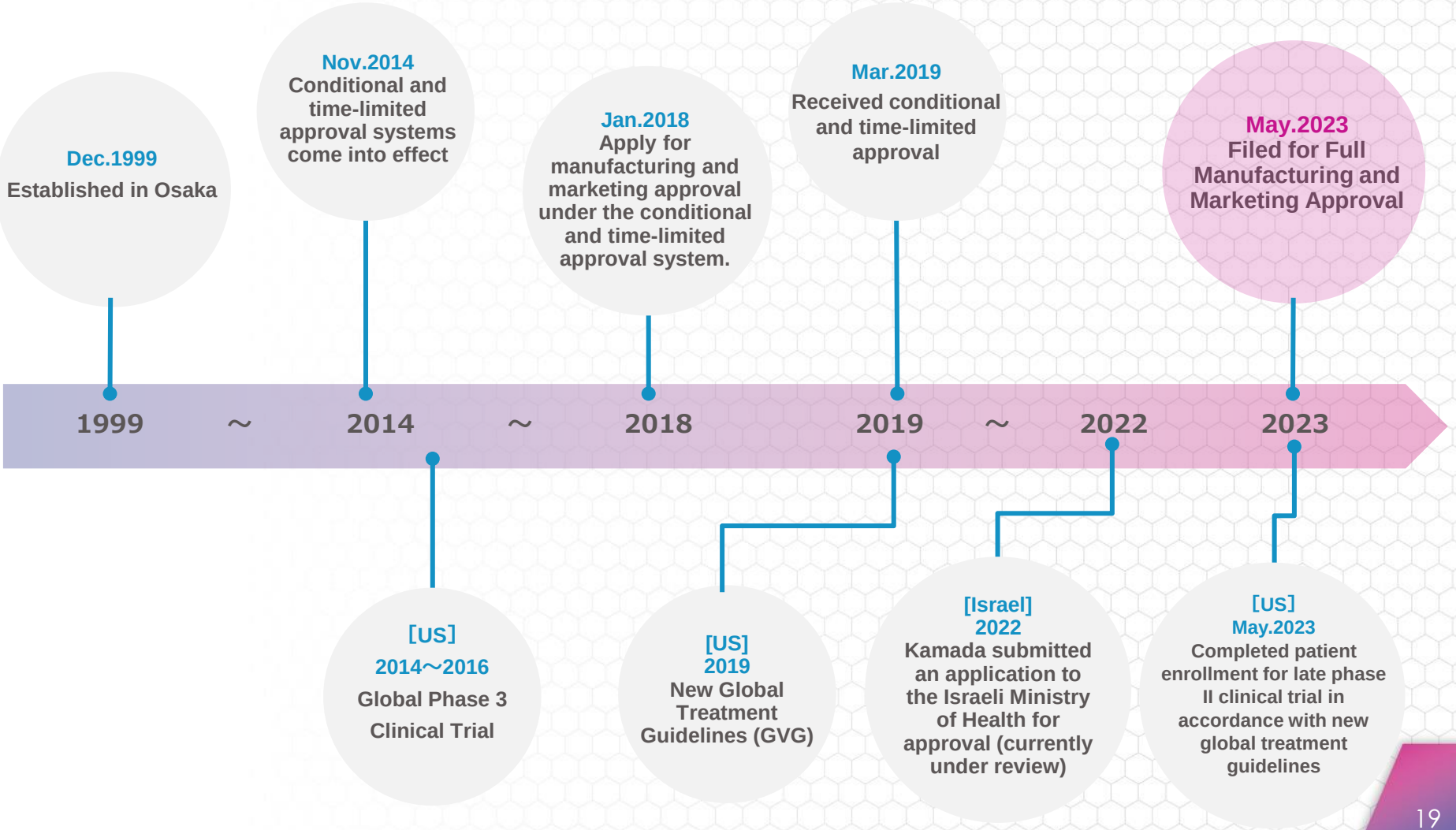
Progress in the Development of Collategene, a Product for HGF Gene Therapy

Filed for manufacturing and marketing approval of Collategene in May 2023

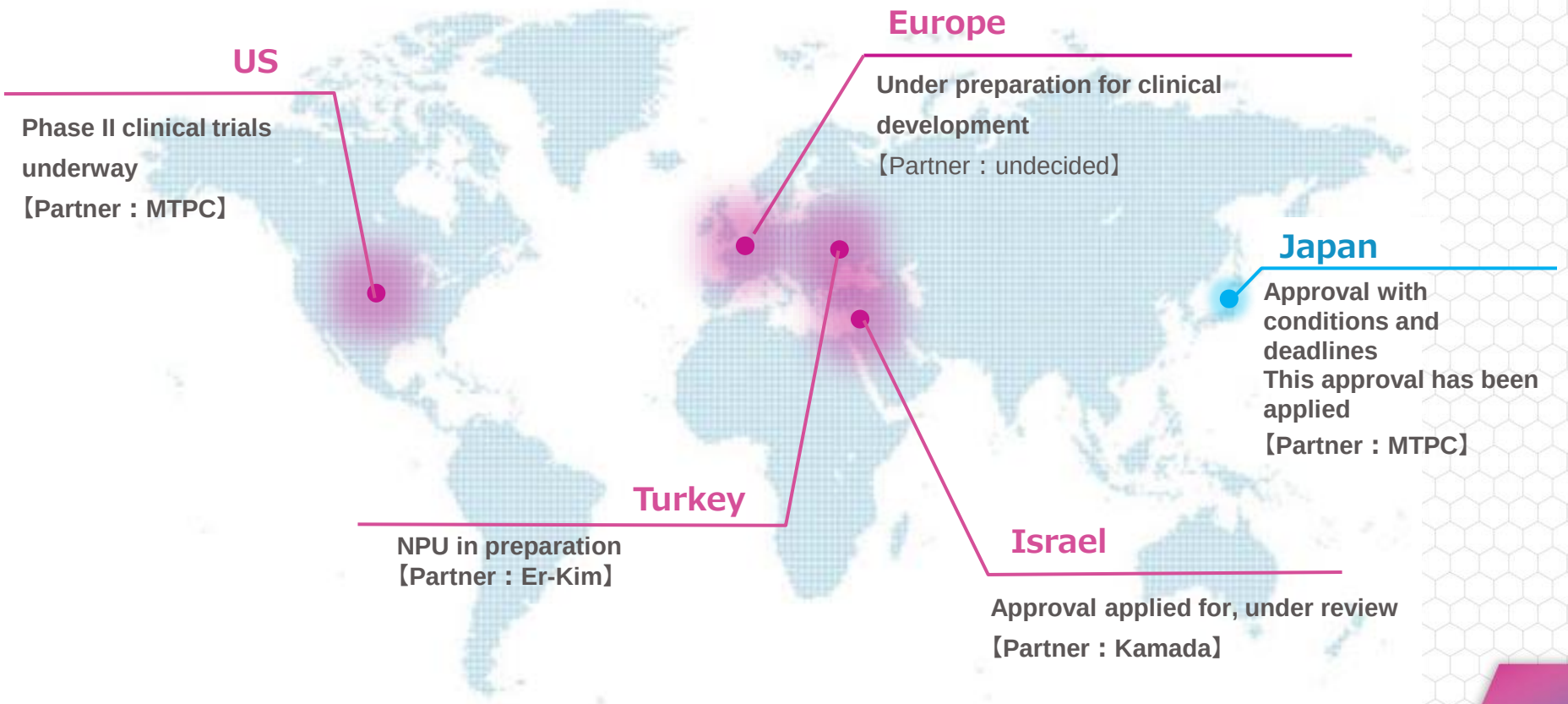
Currently responding to review for approval



Global development of HGF gene therapy products

US Late Phase 2 clinical trial data expected to be released in Q2 2024

Europe Consideration of partners



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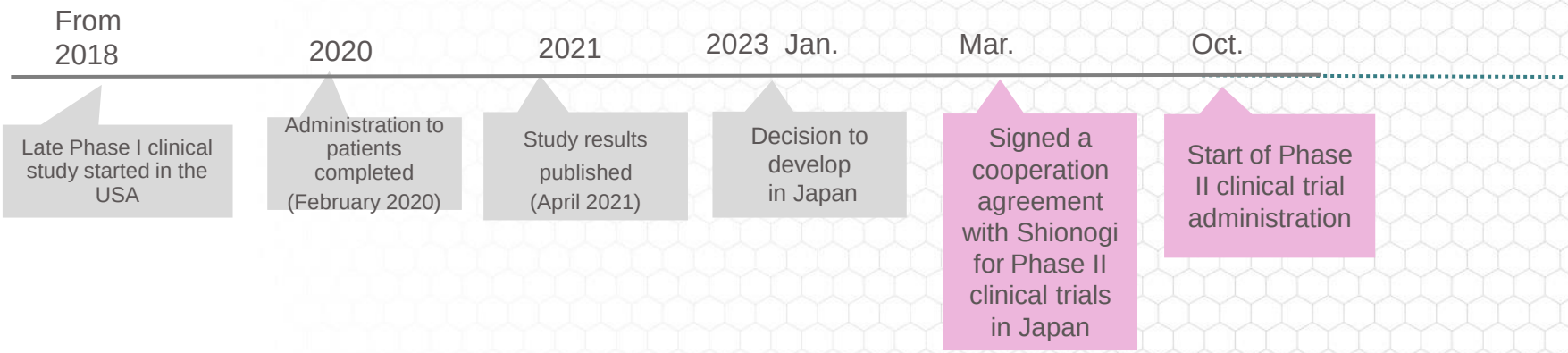
NF-κB decoy oligo DNA

Started Phase II clinical trial administration in Japan

Safety was confirmed by the Independent Data Safety Monitoring Committee for two patients administered in October 2023



Proceeding with enrollment of patients for Phase 2 clinical trials as planned

Applicable disease	Chronic discogenic lumber back pain
Number of patients	1,670,000 (JP) (Source: IQVIA)
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) Signed a cooperation agreement with Shionogi for Phase II clinical trials in Japan (March 2023) Start of Phase II clinical trial administration (October 2023)

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Tie-2 Receptor Agonist

Phase II clinical trials are underway in the U.S.

Phase II clinical trials underway for acute respiratory distress syndrome (ARDS), including viral and bacterial pneumonia such as novel coronavirus and influenza

Independent Data and Safety Monitoring Board (IDSMB) has issued a positive safety evaluation for the ongoing Phase II clinical trial in the U.S.

In clinical trials in the U.S., the IDSMB, a third-party organization independent of the study sponsor, monitors the safe conduct of clinical trials, and the IDSMB conducts safety assessments as needed during the conduct of clinical trials.

Additional Medical Institutions to Conduct Clinical Trials Toward Target Patient Enrollment in Phase II Clinical Trials
Strengthening collaboration with medical institutions based on our clinical trial expertise
Accelerate clinical development

Aiming to complete registration by the end of FY2024

AV-001, a Tie2 receptor agonist, is being developed in collaboration with Canadian biopharmaceutical company Vasomune Therapeutics, Inc.

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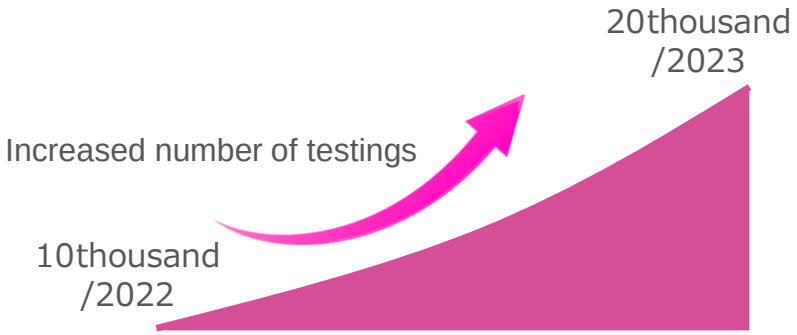
AnGes Clinical Research Laboratory (ACRL)

Sanitary laboratory with the main purpose of testing for rare genetic diseases

AnGes Clinical Research Laboratory

Contracted for expanded newborn screening services*



In the future, we will work to **expand the number of contractors** and **the number of diseases to be tested**.

*Optional Screening Tests offered by the Council for the Advancement of Rare Diseases in Medicine and Research (CReARID)

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)

Trends in Expanded Newborn Screening Tests

In recent years, the development of therapeutic agents for **SCID** (Severe Combined Immunodeficiency Disease) and **SMA** (Spinal Muscular Atrophy) has progressed, and early detection and treatment are expected to prevent the symptoms from becoming more severe.
There has been frequent media coverage of each municipality's response to screening tests

Saga Prefecture will add SMA and SCID to the newborn mass screening test coverage starting in FY2023, with all costs covered by public funds

新生児検査に2難病追加へ　佐賀県、2023年度から費用全額公費で負担

2023/02/23 07:45

中島野愛　大橋諒

画像を拡大する

佐賀県は２０２３年度から、新生児の先天性代謝異常などの病気をみつけるための検査「新生児マススクリーニング検査」の対象に「脊髄性筋萎縮症（ＳＭＡ）」と「重症複合免疫不全症（ＳＣＩＤ）」を加え、費用を全額公費で負担する。二つの難病は、検査手法の確立や治療薬の承認などにより早期に発見すれば、治療が可能になっており、生まれたばかりの命を病から救うことにつなげる。２疾患の検査費全額公費負担は栃木県と並び、全国初の試みとなる見込み。

県はＳＭＡとＳＣＩＤの検査費や検査を周知するための広報費として、開会中の県議会に上程した２３年度一般会計当初予算案に３１５３万円を盛り込んだ。

県こども家庭課などによると、ＳＭＡは遺伝子の一部が欠け、筋肉の萎縮や呼吸困難などの症状が出る進行性の病気で、約２万人に１人が発症する。ＳＣＩＤは遺伝子異常で免疫機能が働きにくく、生まれつき病気にかかりやすくなる難病で、約５万人に１人の患者がいるとされる。国は２０年１０月から、ロタウイルスワクチンを定期予防接種の対象としているが、ＳＣＩＤの子どもが接種を受けると重い副反応の懸念がある。

2023.2.23 佐賀新聞より
https://www.saga-s.co.jp/articles/-/994468

The Administration for Children and Families has decided to implement a new "newborn mass screening test" for two incurable diseases, SMA and SCID, at public expense.

新生児スクリーニング検査、二つの難病追加へ　自治体間の差に課題も

有料記事
後藤一也　2023年11月21日 18時30分

こども家庭庁内にあるイベントスペースの入り口＝2023年4月、東京都千代田区、藤崎麻里撮影

[PR]

赤ちゃんに先天性のまれな病気がないかを調べる「新生児マススクリーニング検査」で、こども家庭庁は、新たに二つの難病について公費で実施する方針を決めた。自治体によって実施状況に差がある現状を改善するねらいがある。準備の整った自治体からスタートさせ、将来的には全国一律で検査できる体制をめざす。

新たに対象となるのは、「脊髄（せきずい）性筋萎縮症（SMA）」と、「重症複合 免疫不全 症（SCID）」で、いずれも患者数は10万人あたり1～2人程度とされる。

SMAは進行性の筋力低下が起きる。SCIDは生まれつき免疫がうまくはたらかず、感染症にかかりやすい。いずれも1歳までに亡くなることもあるが、ここ数年で治療法が進展したことで、早期発見の重要性が増している。独自に検査を導入している自治体も多いが、検査や治療の体制が整わずに導入できていない自治体もあり、格差が指摘されていた。

2023.11.20朝日新聞オンラインより
https://www.asahi.com/articles/ASRCP4W3KRCNUTFL021.html

Angers Clinical Research Laboratory has SCID and SMA as screening diseases

ACRL's Expanded Newborn Screening Test Features

Flexible screening tests for 9 diseases

Screening tests for 9 diseases can be performed, the largest number of test items in Japan
We use this strength to propose inspection packages in accordance with your requests and needs

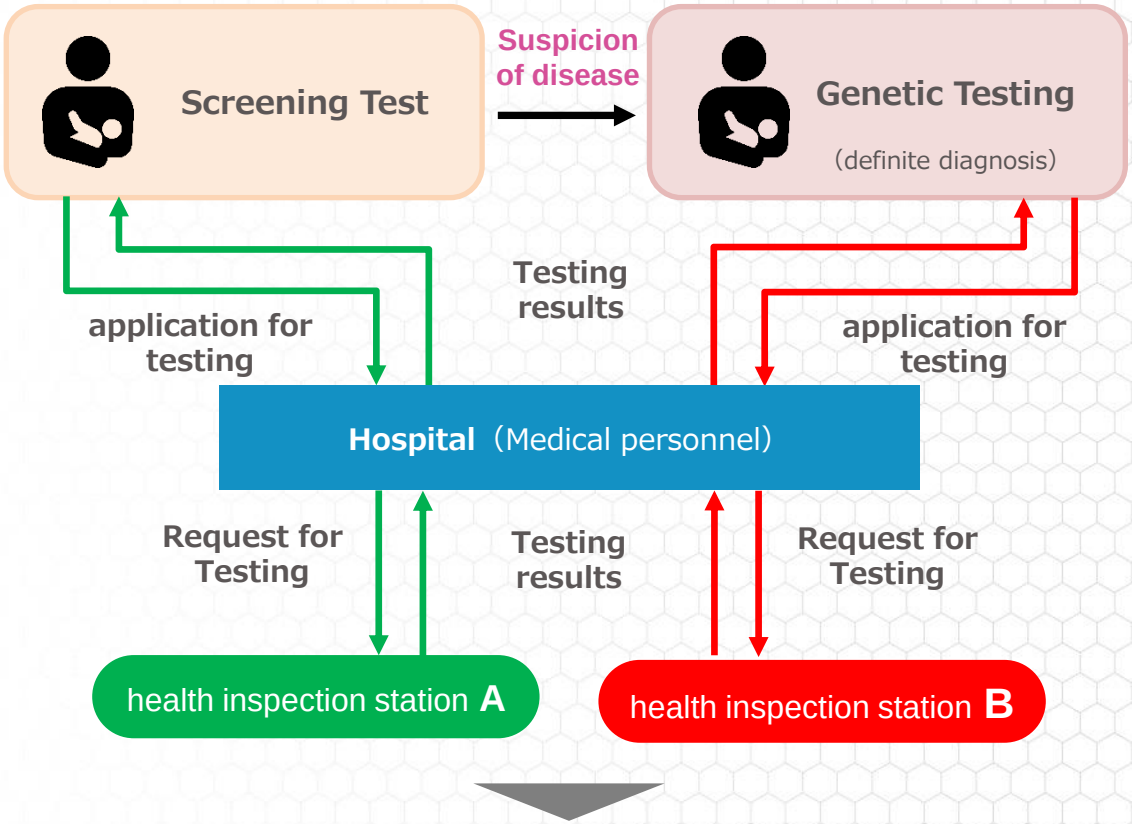
※The table below shows an image of ACRL's ability to undertake inspections in accordance with local government requirements

municipality	Test items	Fabry	Pompe	MPS I	MPS II	MPS IVA	MPS VI	PID/ SCID	SMA	ALD
①	9	ACRL	ACRL	ACRL	ACRL	ACRL	ACRL	ACRL	ACRL	ACRL
②	7	ACRL	ACRL	ACRL	ACRL	ACRL	ACRL	inspection station **A**		ACRL
③	4	ACRL	ACRL	ACRL	ACRL	–	–	inspection station **B**		–

Some municipalities outsource specific packages of testing items, but ACRL,
Contracting for screening tests for all 9 diseases
Only some of the tests for certain diseases are outsourced
ACRL can respond flexibly to your needs

Definitive diagnosis of screening-positive patients

There are no laboratories that can outsource screening and genetic testing for rare genetic disorders, including diseases subject to expanded newborn screening

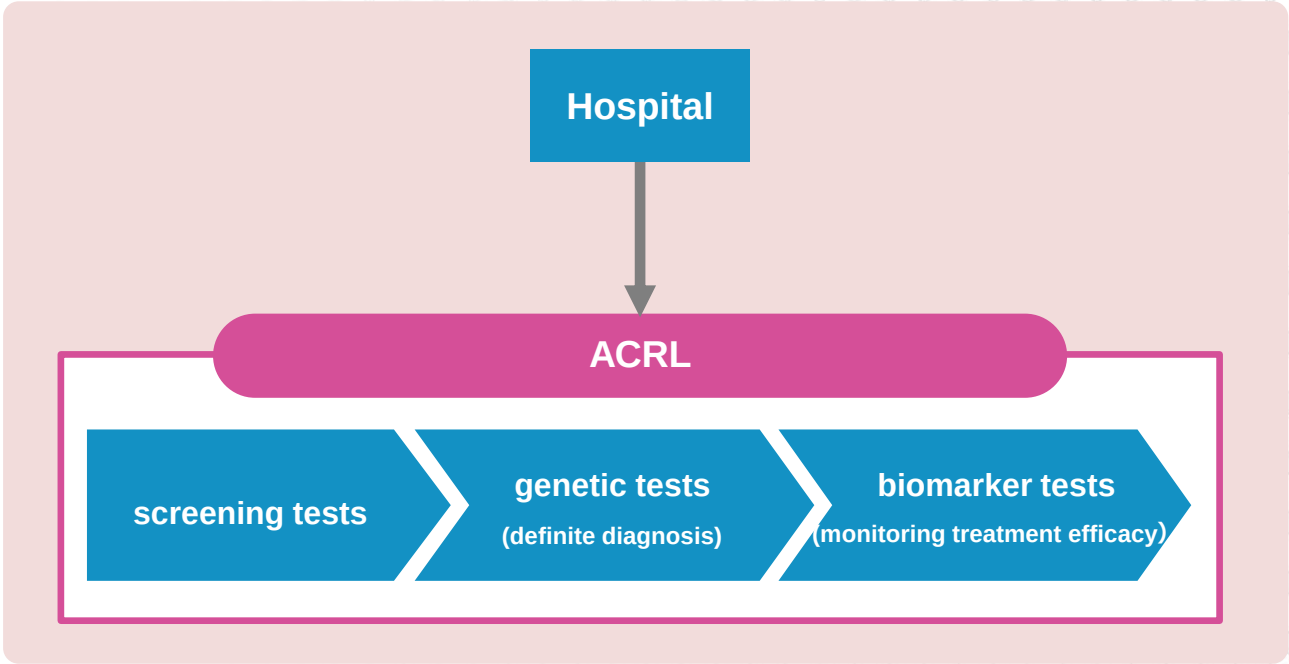


It has become a major burden for medical professionals involved in rare disease treatment

Reduce the burden on medical professionals involved in rare genetic diseases

The only one-stop testing for rare genetic disorders in Japan

While there are few laboratories that perform all the tests for rare genetic diseases due to lack of profitability, ACRL has the necessary systems and functions for rare genetic disease testing, including "screening tests," "genetic tests" for definitive diagnosis of diseases, and "biomarker tests" for monitoring treatment efficacy, without requiring patients and doctors to request multiple laboratories.



ACRL's Immediate Initiatives

Rare Genetic Disease Testing

Screening Tests

Testing newborns for possible genetic disorders

We are working to develop new testing methods to reduce false positives in screening

Genetic Tests
(definite diagnosis)

If screening tests indicate possible disease, determine the presence or absence of disease

In FY2023, we established a genetic testing system to begin offering one-stop services in testing for rare genetic diseases

Biomarker Tests
(monitoring treatment efficacy)

Provide data to determine the effectiveness and improvement of treatment after the start of treatment

Newborn Mass Screening

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

Extended newborn screening

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

Discussions will continue with the aim of starting direct contracting with municipalities and related institutions during the first half of 2024

ACRL Facility Tour" for the press (Jan. 2024)

Held a tour of the facility for members of the press to gain an understanding of the Company's efforts to treat rare genetic diseases

ACRL staff gave an overview of rare genetic diseases and ACRL's work

Dr. Okuyama, ACRL's supervising physician and CReARID representative director, spoke about the status and problems of newborn extended screening

03

Other developed products, collaboration with partner companies

DNA Vaccine

Hypertension vaccine

Phase I/II early phase clinical trial conducted in Australia

Patient dosing for clinical trials completed in 2020
Results of follow-up study show no safety issues

Investigate measures to improve plasmid DNA expression, etc.

Intranasally administered vaccine for novel coronavirus infection

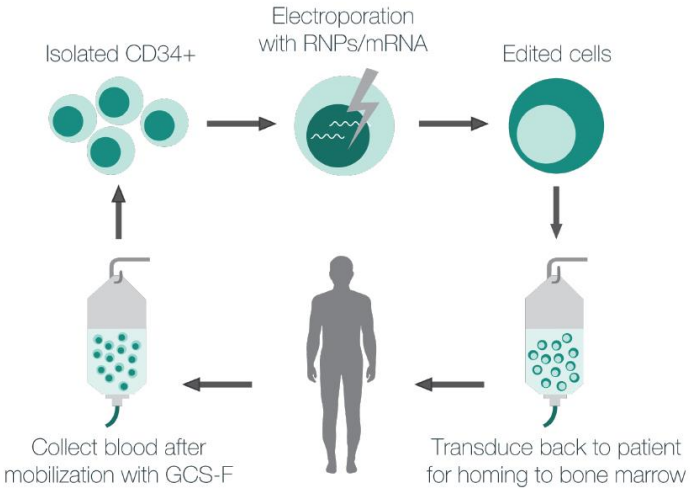
Joint research with Stanford University, U.S.A. from 2022

Review of platform, including improvement of plasmid expression and transduction efficiency

Development of intranasal dosage forms, including development of drug delivery systems

Aiming to treat ELANE-related severe congenital neutropenia requiring avoidance of off-target effects.

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

Emendo's R&D Structure

Avoiding geopolitical risks and establishing a structure for clinical trials in the U.S.

Prolonged conflict in the Gaza Strip, which began in October 2023, exposes geopolitical risks to development at Emendo's R&D site (EmendoBio Research and Development Ltd.)

For the development of nuclease, the R&D structure will be changed from labor-intensive to knowledge-intensive by utilizing machine learning

Recognized the importance of accelerating preparations for the start of clinical trials in the U.S.

Accelerate preparations for clinical trials in the U.S. and downsize (continue) the R&D base in Israel, while focusing on products for which R&D is progressing, such as **ELANE-related severe congenital neutropenia**, and **strengthen the structure in the U.S.** with the aim of **licensing out genome editing technology**, etc.

Collaboration with partner companies

miRaX Therapeutics

Acquired an option right to negotiate for an exclusive license for intellectual property rights related to research on micro RNA inhibitors on a preferential basis

Investigating the drug discovery potential of Tough decoy, a nucleic acid medicine targeting micro RNA

BioSafety Research Center Inc.

Signed a joint research agreement to build an evaluation model using zebrafish and establish an evaluation method in 2022

Create a TGZF model that can confirm GFP expression by inflammatory stimuli and response to drugs, and commercialize the TGZF model by administering a drug that we have developed

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	Application

■ 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)			
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 lumber back pain			Completed				
DNA vaccine	Australia	–	Injectable	Hypertension			Completed				
DNA vaccine	US	–	Intranasal formulation	COVID-19 / ADRS	On going						
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					Approved	

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