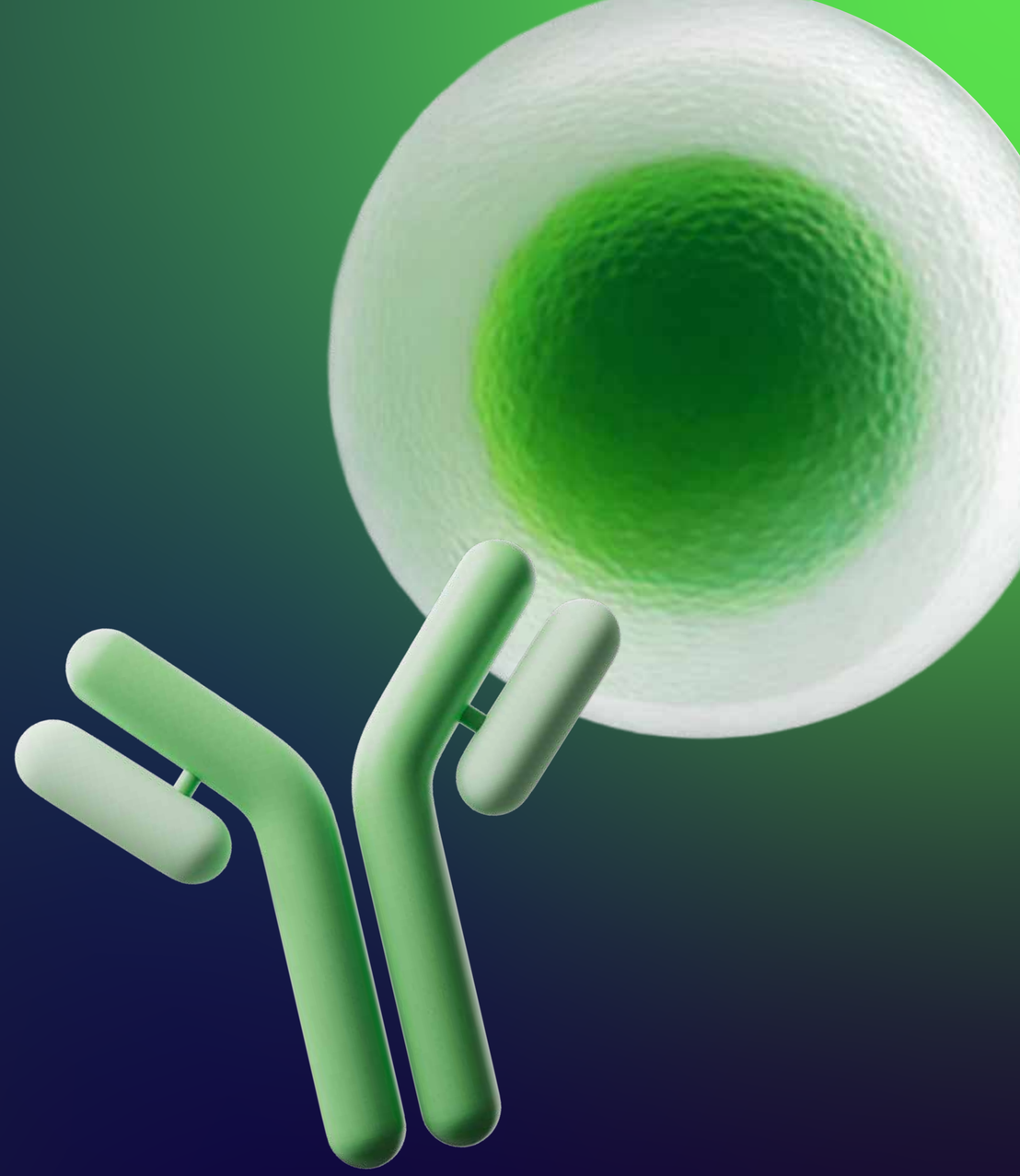
CELLTRION

# Daring to go Beyond

English



# Powered by innovation, trusted worldwide

# Company Introduction

Celltrion is a global biopharmaceutical company that researches, develops and manufactures antibody biosimilars and novel therapeutics. By successfully developing the world's first monoclonal antibody biosimilar, Celltrion has opened new frontiers in the biopharmaceutical industry, delivering advanced treatment options that improve the quality of life for patients worldwide. Leveraging world-class biotechnology and forward-looking business strategies, Celltrion continues to grow as a fully integrated biopharmaceutical leader, committed to enhancing health and well-being globally.

**2002**
Year of establishment

**3,184**
Number of employees (as of Q2 2026)

**12** products
Approved products

**110 +** countries
Global presence

**250,000L**
Total production capacity

**99%**
Manufacturing success rate

# Milestones

## 2002-2012

**2002. 02** Celltrion founded

**2005. 07** Plant 1 completed (50,000L)

**2007. 12** Plant 1 receives cGMP facility approval by US FDA

**2011. 10** Plant 2 completed (90,000L)

## 2013-2017

**2013. 08** Remsima gets Europe EMA approval

**2015. 06** Plant 1 & 2 receive approval by US FDA on all cGMP manufacturing facilities

**2016. 10** Remsima' s accumulated exports reach 1 trillion won

**2017. 02** Truxima gets Europe EMA approval

## 2018-2022

**2018. 02** Herzuma gets Europe EMA approval

**2019. 05** Expansion of Plant 1 completed (additional 50,000L)

**2020. 02** Reached KRW 1 trillion in annual sales

**2021. 02** Yuflyma receives approval by Europe EMA

**2022.08** Vegzelma receives approval by Europe EMA

## 2023-Present

**2023. 05** Celltrion Global R&D Center completed

**2023. 10** Remsima SC (US product name: Zymfentra) received approval by US FDA as novel therapeutics

**2023. 11** Plant 3 completed (60,000L)

**2024. 01** Celltrion Inc. & Celltrion Healthcare Co., Ltd. merger completed

**2024. 12** Achieved a record number of product launches with 12 approvals secured

Remsima reaches KRW 1 trillion in yearly sales, marking Korea's first blockbuster drug

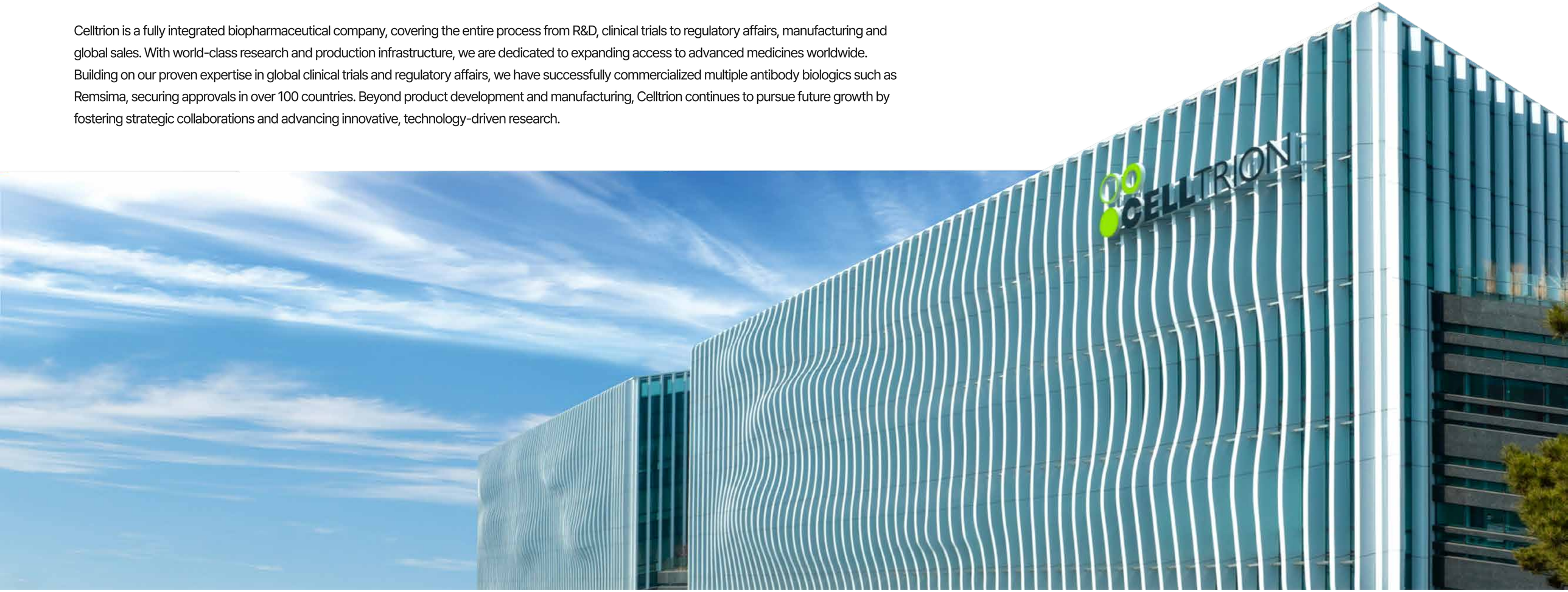
**2025. 12** Secured production facility in the U.S

**2026. 01** Established Celltrion Branchburg production facility in New Jersey, US


# Seamless capabilities, from lab to life

# Business Overview

Celltrion is a fully integrated biopharmaceutical company, covering the entire process from R&D, clinical trials to regulatory affairs, manufacturing and global sales. With world-class research and production infrastructure, we are dedicated to expanding access to advanced medicines worldwide. Building on our proven expertise in global clinical trials and regulatory affairs, we have successfully commercialized multiple antibody biologics such as Remsima, securing approvals in over 100 countries. Beyond product development and manufacturing, Celltrion continues to pursue future growth by fostering strategic collaborations and advancing innovative, technology-driven research.



# R&D

Building on the advanced therapeutic capabilities of antibody-based medicines, Celltrion is driving the development of biosimilars and novel biologics. In parallel, we pursue innovative platform research to elevate drug performance and deliver greater convenience for patients.

## Antibody Biologics

### Biosimilars

Celltrion's biosimilars demonstrate equivalent efficacy and safety to reference biologics, offering more affordable treatment options and expanding patient access to advanced therapies.

### Novel therapeutics

Leveraging next-generation technologies such as novel antibodies, ADCs, and multispecific antibodies, Celltrion is expanding the scope of antibody-based treatments to address more diseases.

## Platform Technologies

### Cell line platform

Celltrion has developed a proprietary cell line platform with outstanding productivity and stability, enhancing the production of high-quality antibody therapeutics while shortening the development timeline for production cell lines.

### Microbiome therapeutics

Celltrion is developing microbiome-based therapeutics that utilize beneficial microorganisms, such as gut microbiota, to modulate immune balance and open new possibilities for treating hard-to-cure diseases.

### Formulation development

Through advanced formulation technologies, including high-concentration solutions, we improve drug stability and patient convenience, expanding therapeutic options across diverse disease areas.

# Novel Therapeutics Development

Celltrion is advancing next-generation biopharmaceuticals with precision-targeted technologies designed to effectively address specific diseases, offering new therapeutic possibilities through superior efficacy.

## ADC

### Biobetter ADC

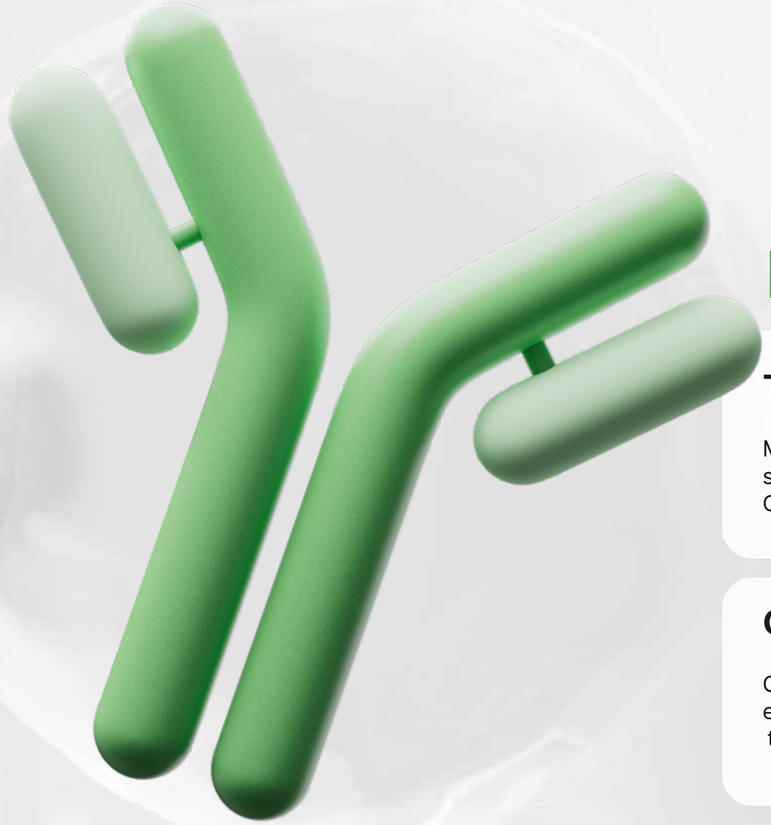
Celltrion improves the therapeutic index of ADCs by leveraging the bystander effect to enhance tumor-targeting efficacy.

### Bispecific ADC

By simultaneously targeting two or more antigens, Celltrion's bispecific ADCs are designed to overcome cancer heterogeneity and improve treatment outcomes.

### Dual-payload ADC

Through innovative payload combinations, Celltrion achieves synergistic efficacy and extends therapeutic effects across diverse cancer types.



## Multispecific antibody

### Tumor-selective MsAb

Multispecific antibodies are being designed with enhanced tumor selectivity to minimize on-target, off-tumor toxicity, as part of Celltrion's ongoing development of safer cancer immunotherapies.

### Conditionally-active MsAb

Celltrion is advancing conditionally active multispecific antibodies that expand cytotoxic activity to low-antigen-expressing cancer cells, increasing treatment response and broadening the eligible patient population.

### Other Immuno-oncology MsAb

Celltrion maximizes the therapeutic potential of tumor-killing immune cells through multispecific antibody strategies in immuno-oncology.

# Production Facilities

**Plant 1** 12,500L x 8 lines

## 100,000L

- Asia's first animal cell culture facility approved by the US FDA

**Plant 2** 15,000L x 6 lines

## 90,000L

- Capable of manufacturing everything from drug substances to drug products

**Plant 3** 7,500L x 8 lines

## 60,000L

- Specializes in multi-product, small-batch production to accommodate a diverse product mix

## Total Production Capacity

## 250,000L

Celltrion has a production capacity of 250,000L capable of manufacturing everything from drug substances to drug products. We have acquired US FDA and Europe EMA cGMP certifications on all facilities after being the first in Asia to operate FDA cGMP certified animal cell culture facilities. Plants 1 and 2 enable large-scale production, while Plant 3 specializes in multi-product, small-batch production, allowing us to respond swiftly to diverse manufacturing needs.

Celltrion manages its production environment and processes in line with the latest global regulatory standards, producing high-quality biopharmaceuticals through advanced technologies and strict quality policies. We maintain product quality through rigorous quality control activities and hold a long-standing record of contamination-free and incident-free production.

CELLTRION

# Quality Policy

Celltrion's 250,000L production facilities, capable of manufacturing both drug substances and drug products, operate under stringent quality policies aligned with the latest global cGMP standards, including those set by the US and Europe.

01

## Plan

- Risk assessment analysis
- Resource analysis
- Strategic analysis

02

## Performance

- Education, documentation
- Validation, calibration
- Execution

03

## Monitoring

- Internal audit
- Trend monitoring
- Deviation/change control

04

## Evaluation

- Convene quality council
- Trend analysis
- Regulatory inspections
- Product quality review

05

## Improvement

- Immediate improvement
- Corrective Action & Preventive Action
- Procedure update

# Distribution Network

Celltrion's biopharmaceuticals reach patients in over 100 countries, including the US and Europe, through our rapidly growing direct distribution network. Our mission to achieve global access ensures quality medical care at reasonable costs, alleviating financial burdens on public healthcare systems.

## Market share in Europe

| | |
|---|---|
| Remsima | 60% |
| Truxima | 30% |
| Herzuma | 19% |

(as of Q3 2025)

## Market share in the US

| | |
|---|---|
| Remsima | 30% |
| Truxima | 35% |
| Vegzelma | 9% |

(as of Q4 2025)

# Proven therapies for broader access

# Products

## Remsima

World's 1st monoclonal antibody biosimilar

2013 EMA approved | 2016 FDA approved


**Indication**
Rheumatoid arthritis, inflammatory bowel disease

## Truxima

Sold in about 90 countries including the US, EU

2017 EMA approved | 2018 FDA approved


**Indication**
Non-Hodgkin's Lymphoma, rheumatoid arthritis

## Herzuma

Sold in about 90 countries including the US, EU

2018 EMA approved | 2018 FDA approved


**Indication**
Metastatic breast cancer, metastatic gastric cancer

## Remsima SC *US sales name: Zymfentra

World's first SC version of infliximab

2019 EMA approved | 2023 FDA approved


**Indication**
Rheumatoid arthritis, inflammatory bowel disease

## Yuflyma

First-ever high-concentration version

2021 EMA approved | 2023 FDA approved


**Indication**
Rheumatoid arthritis, inflammatory bowel disease

## Vegzelma

Sold in about 35 countries including the US, EU

2022 EMA approved | 2022 FDA approved


**Indication**
Metastatic colorectal cancer, non-small cell lung cancer, metastatic breast cancer

# Products

## Omlyclo

Marketing authorization
in US, EU, Korea

2024 EMA approved · 2025 FDA approved


**Indication**

Asthma, urticaria

## Eydenzelt

Marketing authorization
in US, EU

2025 EMA approved · 2025 FDA approved


**Indication**

Diabetic macular edema,
wet age-related macular degeneration

## Steqeyma

Marketing authorization
In US, EU, Korea

2024 EMA approved · 2024 FDA approved


**Indication**

Psoriasis,
inflammatory bowel disease

## Stoboclo

Marketing authorization
in US, EU, Korea

2025 EMA approved · 2025 FDA approved


**Indication**

Osteoporosis

## Osenvelt

Marketing authorization
in US, EU, Korea

2025 EMA approved · 2025 FDA approved


**Indication**

Osteoporosis

## Avtozma

Marketing authorization
in US, EU, Korea

2025 EMA approved · 2025 FDA approved


**Indication**

Rheumatoid arthritis,
active systemic juvenile idiopathic arthritis

# Pipeline

## Biosimilar

### Darzalex biosimilar

**CT-P44**

| | |
|---|---|
| **Current status** | Clinical Phase 3 |
| **INN** | Daratumumab |
| **Indication** | Multiple myeloma, etc. |

### Keytruda biosimilar

**CT-P51**

| | |
|---|---|
| **Current status** | Clinical Phase 3 |
| **INN** | Pembrolizumab |
| **Indication** | Melanoma, lung cancer, stomach cancer, cervical cancer, etc. |

### Ocrevus biosimilar

**CT-P53**

| | |
|---|---|
| **Current status** | Clinical Phase 3 |
| **INN** | Ocrelizumab |
| **Indication** | Multiple sclerosis, etc. |

### Cosentyx biosimilar

**CT-P55**

| | |
|---|---|
| **Current status** | Clinical Phase 3 |
| **INN** | Secukinumab |
| **Indication** | Psoriasis, etc |

## Novel therapeutics

### New drug

**CT-P70**

| | |
|---|---|
| **Current status** | Clinical Phase 1 |
| **INN** | cMet Target ADC |
| **Indication** | Solid cancer |

### New drug

**CT-P71**

| | |
|---|---|
| **Current status** | Clinical Phase 1 |
| **INN** | Nectin-4 Target ADC |
| **Indication** | Bladder cancer, prostate cancer, breast cancer |

# Pipeline

## Novel therapeutics

**New drug**

**CT-P72**

| | |
|---|---|
| **Current status** | Clinical Phase 1 |
| **INN** | HER2 x CD3 |
| **Indication** | Solid cancer |

**New drug**

**CT-P73**

| | |
|---|---|
| **Current status** | Clinical Phase 1 |
| **INN** | Tissue Factor Target ADC |
| **Indication** | Cervical cancer, head and neck cancer, colon cancer |

# Enhancing values of health and welfare

# ESG Strategy Roadmap

**2022**
**Introduce ESG management**
- Establish ESG governance
- Identify priority improvement tasks through ESG performance assessment
- Set ESG goals and directions

**2025**
**Expand ESG management**
- Undertake ESG activities and respond to ESG disclosure needs
- Attain phase-specific goals for ESG
- improvement tasks and manage performance

**2030**
**Stabilize ESG management**
- Strengthen ESG management monitoring
- Expand and enhance ESG management scope

# ESG Management System

## Strategic approach

### Environmental

**Green management for a sustainable future**

To realize Green Management for a Clean Future Environment, we are committed to enhancing our environmental performance through strict regulatory compliance, strengthened management systems, and expanded eco-friendly investments. We minimize the environmental footprint of our products across their life cycle by optimizing resource use and conduct risk and financial impact assessments on climate change and biodiversity, aiming for carbon neutrality and net-positive outcomes in line with our mid- to long-term roadmap.

### Social

**Prosperity management through social responsibility**

Celltrion is dedicated to upholding the human rights of all stakeholders in line with its Human Rights Policy and fostering an inclusive, discrimination-free corporate culture.As a leader in the biosimilar market, we strive to expand global access to high-quality medicines. Furthermore, we strive to establish a sustainable value chain by delivering ESG training across our supply network and strengthening risk management initiatives.

### Governance

**Exemplary governance**

Celltrion has established clear and rigorous standards that guide all employees in their daily responsibilities, ensuring the effective implementation of compliance management to cultivate a transparent and ethical corporate culture. Our dedicated Compliance Department further reinforces this framework by overseeing critical areas-including anti-corruption, fair trade, intellectual property, data privacy, labor and human resources, environmental safety, and healthcare-to proactively mitigate potential risks and strengthen company-wide compliance initiatives.

## Key tasks

- Expand waste recycling and wastewater reuse
- Transition to eco-friendly packaging materials at each manufacturing site
- Invest in eco-friendly vehicles and energy-saving facilities

- Conduct leadership development programs for women
- Ensure fair and reasonable pricing of products
- Increase support for supplier capability-building programs

- Implement a board performance evaluation system
- Unify the integrated risk management process
- Improve disclosure of compliance control standards

# Position as comprehensive global biotechnology enterprise

Celltrion continues to advance as a global, fully integrated biopharmaceutical company through relentless R&D, bold investments, and an unwavering spirit of challenge. Building on our pioneering achievements, we strive to shape a healthier future through differentiated growth initiatives.

**STEP 1**

## Secure base technologies and infrastructure

**STEP 2**

## Development of in-house products

- Development and sale of antibody biosimilars

**STEP 3**

## Expansion of business areas

- Strengthening new drug and biosimilar pipelines
- Expansion of global healthcare distribution network
- Discover new growth driver backed by Global R&D Center

**STEP 4**

## Become a top 10 global biopharmaceutical enterprise