

# **Supplementary Information for Financial Results FY12/22**

**Feb. 14, 2023**



**To accelerate drug discovery and development of mAb  
for therapeutics to overcome current medical unmet-needs**

**Chiome Bioscience Inc.**



- 1. Overview of FY12/22 “Financial results”**
- 2. Overview of FY12/22 “Operation highlights”**

**Appendix.**

**Corporate information**

**Pipeline information**



## **Overview of FY12/22 “Financial results”**

# Financial results: Profit and Loss



(JPY in millions)

	FY2021	FY2022	Increase (decrease)	Main reasons for increase / decrease
Net sales	712	630	(82)	
Drug Discovery & Development	103	-	(103)	Upfront payment of the out-licensing contract was recorded in FY12/21
Drug Discovery Support	609	630	20	
COS/SGA	2,047	1,889	(157)	
R&D Expense	1,312	1,135	(176)	Decrease in CMC related costs in F12/22
Other costs	735	753	18	
Operating Loss	(1,334)	(1,258)	75	
Ordinary Loss	(1,329)	(1,243)	85	
Net Loss	(1,479)	(1,242)	237	Valuation loss on investment securities was recorded in FY12/21

# Financial results: Balance Sheet



(JPY in millions)

	As of Dec. 31, 2021	As of Dec. 31, 2022
Current assets	2,216	2,092
(Cash on hand in banks)	1,790	1,727
(Other current assets)	425	364 <sup>*1</sup>
Non-current assets	122	123
Total assets	2,339	2,215
Current Liabilities	392	370
Non-current liabilities	53	54
Total liabilities	446	424
Total net assets	1,893	1,790
Total liabilities and net assets	2,339	2,215

## Explanation of balance sheet

\*1 Upon completion of manufacturing of study drugs for CBA-1535, advance payments were reversed and charged to the current period as an expense

# Financial results: Cash Flows



(JPY in millions)

	FY2021	FY2022
Cash flows from operating activities	(1,131)	(1,191) <sup>*1</sup>
Cash flows from investing activities	(35)	-
Cash flows from financing activities	271	1,127 <sup>*2</sup>
Net increase (decrease) in cash and cash equivalents	(895)	(63)
Cash and cash equivalents as of the beginning of the year	2,686	1,790
Cash and cash equivalents as of the end of the year	1,790	1,727

## \*1 Cash flows from operating activities

Expenses for clinical development for CBA-1205, CMC development for CBA-1535 and research for drug discovery, SG & A expenses.

## \*2 Cash flows from financing activities

Proceeds from issuance of shares resulting from exercise of 18<sup>th</sup> subscription rights to shares.



## **Overview of FY12/22 “Operation highlights”**



**CBA-1205 : Phase 1 study in progress. Longer than 18 months SD(stable disease) assessment\* in patients who are refractory to standard treatments in the first part of the study.**

\*Final analysis results yet to be completed.

**CBA-1535: Phase 1 clinical study of Tribody™ in cancer patients started. This is the first clinical study to assess safety and efficacy of Tribody™ format.**

**In drug discovery projects, novel Tribody™ antibodies were designed and generated. A new pipeline, PTRY, targeting “5T4×CD3×PD-L1” is in preclinical research.**

**Completed new patent applications for the oncology project and CNS project.**

**A service agreement with option contract with Rohto Pharmaceutical Co. Ltd. has been concluded**

# Operation highlights



## Drug Discovery and Development – Pipeline

### CBA-1205

Humanized afucosylated  
anti-DLK1 antibody

- First part of Phase I clinical study, dose escalation, has been completed. SD (stable disease) duration longer than 18 months has been confirmed. Decision was made to move to the second part of Phase I study.
- The second part, dosing to patients with hepatocellular carcinoma is in progress.

### CBA-1535

Humanized anti 5T4 & CD3  
trisppecific antibody

- Phase 1 study in cancer patients initiated in June 2022.
- Dosing to the patients with solid tumors has started at the National Cancer Center Hospital and Shizuoka Cancer Center. Dose escalation part is in progress.

### PCDC

humanized anti-CDP1  
antibody

- Promoting out-licensing activities mainly in the field of ADC applications.
- Progressing in contacting out-licensing candidate companies at conferences in Japan and abroad.

### Discovery Projects

- A new patent was filed, and a paper was published on "PTRY", our new drug discovery project of Tribody™.
- New patent applications filed for oncology and central nervous system areas we have been focusing on.

## Pipeline - Out-Licensed programs

### LIV-2008

Humanized anti-TROP2  
antibody

- License agreement termination agreed with Henlius (January 27, 2023). Out-licensing activities will be carried out together with other pipelines.

### ADCT-701

- ADCT and the National Cancer Institute are preparing for clinical studies targeting neuroendocrine carcinoma. The studies are scheduled to begin in 2023 (information from ADCT website).



## Drug Discovery Support Business

### Deals with pharmaceutical companies

- Carrying out business development with new pharmaceutical companies as well as strengthening businesses with existing clients. A new contract (a service agreement with an option contract) with Rohto Pharmaceutical Co. Ltd. has been concluded as of July 11, 2022.
- Launch of the 3<sup>rd</sup> diagnostic kit developed with ADLib<sup>®</sup> antibodies by Fujirebio Inc. Period to receive royalty payments from the company is until July 28, 2023, when the patent expires.

## Core Technology

### ADLib<sup>®</sup> system Tribody<sup>™</sup>

- Publication of the paper
  - Research results on cancer immunotherapy using Tribody<sup>™</sup> technology.  
<https://www.mdpi.com/1422-0067/23/7/3466>  
<https://jeccr.biomedcentral.com/articles/10.1186/s13046-022-02474-3>
  - Research results on Affinity Maturation in ADLib<sup>®</sup>  
<https://www.tandfonline.com/doi/full/10.1080/19420862.2022.2122275>
- Participating in a research program supported by a grant from the Japan Agency for Medical Research and Development (AMED), (Research on infectious diseases<sub>7</sub> and improvement of ADLib<sup>®</sup> system). Subsidy income of 20 million yen in FY2022.
- ADLib<sup>®</sup> Notice of Allowance
  - Patent for a method of promoting diversification of the variable region of antibodies (Japan, US)
  - Antibody acquisition methods (Europe)

# Drug Discovery and Development - Pipeline



## Out-Licensed Product

Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Partner
ADCT-701 (LIV-1205 ADC)	DLK-1	Oncology /ADC				2017.9~ 

## In-house developed product

★ **First in class**    ★★ **World first drug discovery modality moving into clinical phase**

Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Status
★ CBA-1205 (ADCC enhanced)	DLK-1	Oncology				Phase 1
★★ CBA-1535 (Tribody™)	5T4×CD3 ×5T4	Oncology				Phase 1

## License candidate and drug discovery project

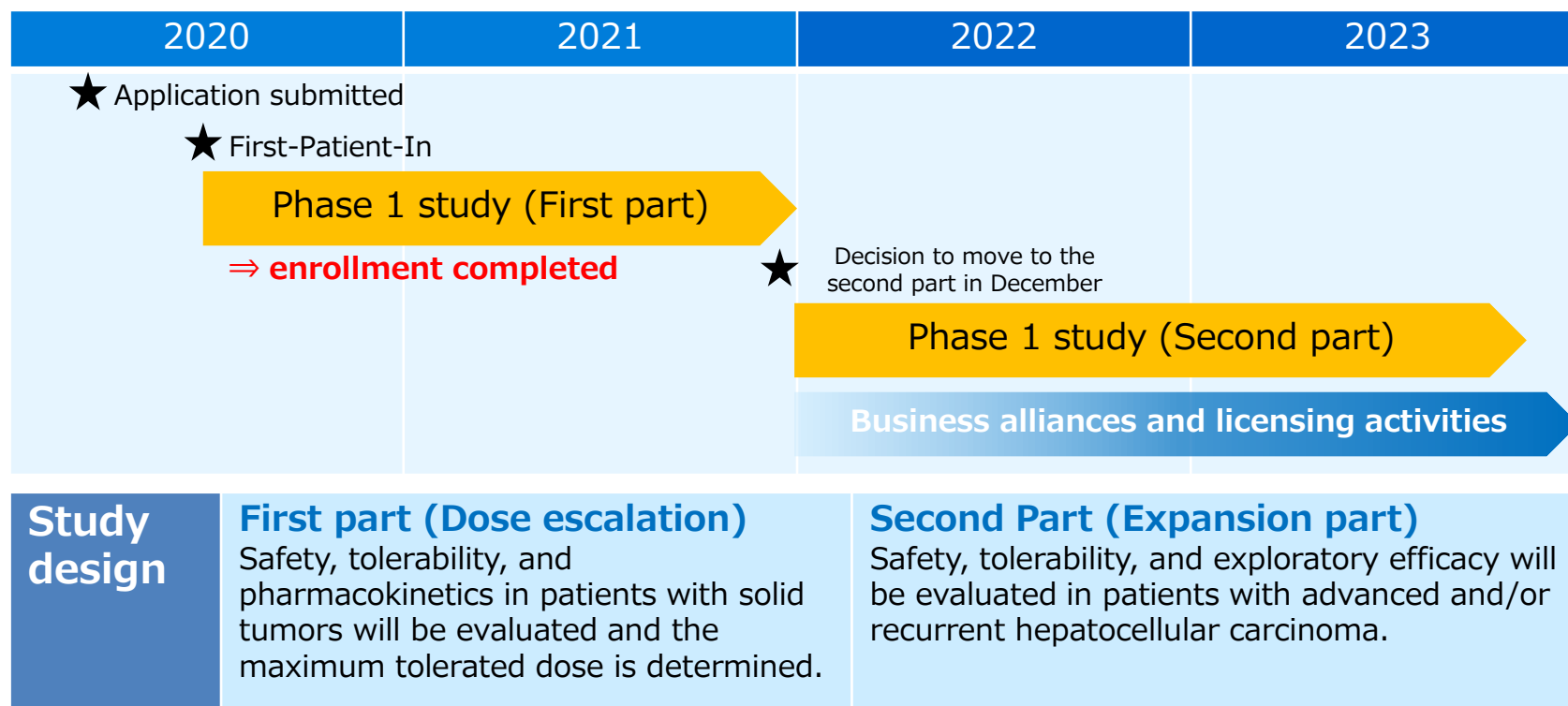
Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Status
★ PCDC	CDCP1	Oncology /ADC				Licensing opportunity
PTRY	5T4×CD3 ×PD-L1	Oncology				Patent application completed New pipeline
★ BMAA	SEMA3A	undisclosed				Licensing opportunity
LIV-2008 /2008b	TROP-2	Oncology				Licensing opportunity
Discovery PJ/ Drug discovery research	Undisclosed	Oncology, CNS, autoimmune diseases, etc.	※			—

※ Completed new patent applications for the oncology project and CNS project.

# CBA-1205 Phase 1 study



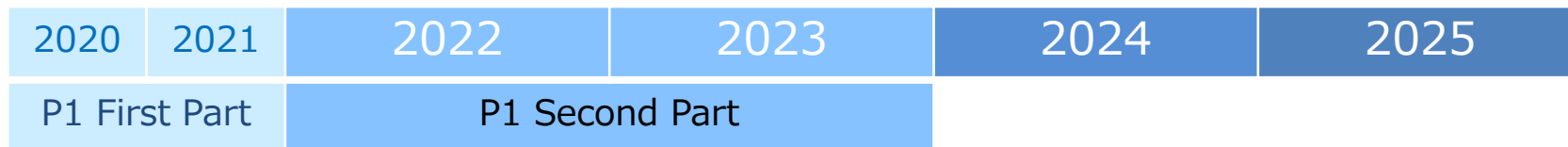
**First part of Phase I clinical trial has been completed.  
Enrollment of patient cases with hepatocellular carcinoma is in progress**



- No serious adverse reactions reported
- **CBA-1205: SD (stable disease) duration longer than 18months has been confirmed.**

- Confirmation of signal of efficacy during the second part will be the key for early out-licensing

# CBA-1205 Out-licensing plan



Targeted time frame for out-licensing

## Out-licensing candidates: 2 different types

Companies looking to expand their development pipeline as early as possible

Companies focused on business feasibilities and probability of success



Possible points for evaluation and consideration



- 1<sup>st</sup>-in-class (original drug)
- High safety in humans
- Patents granted in major regions
- Manufacturing method established, information for clinical studies in place

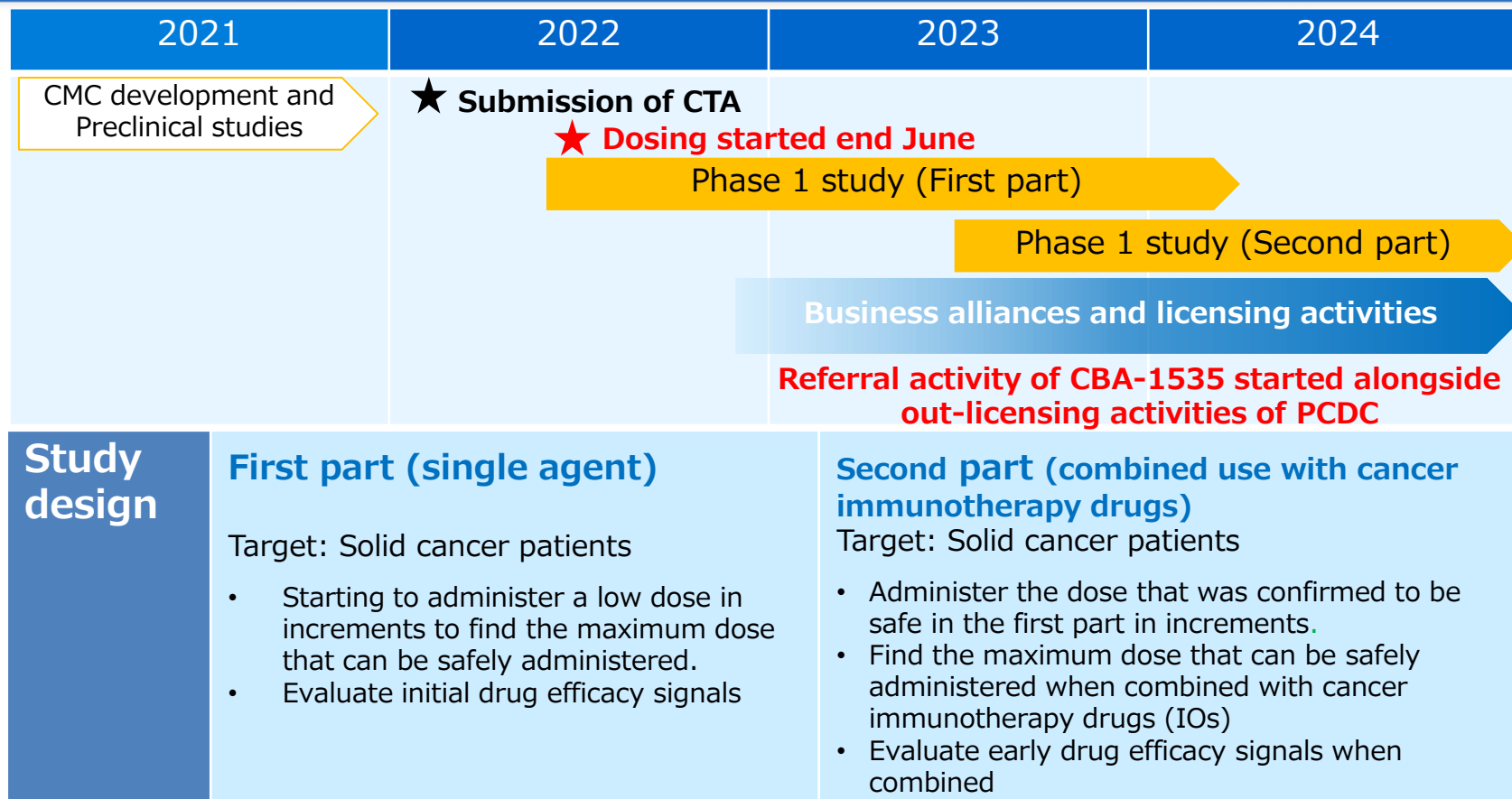
- The response rate in patients
- Biomarker
- Comparison with other drugs, advantages
- Expansion of cancer types, business possibilities

**Upfront payment ≤ Upfront payment**

 **Expectations for a surplus in a single year by out-licensing in early-stage or after P1**



## Dosing for patients started in CBA-1535 Phase I study



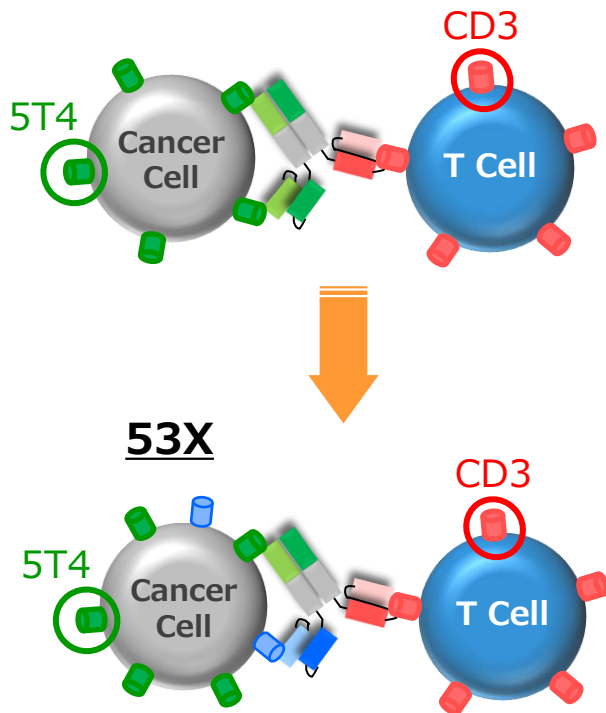
### Aims of this development plan

- This study is designed to confirm if CBA-1535 satisfies clinical needs such like safety and efficacy fastest by adopting combination use of IO in Phase 1
- Confirmation of safety in this study as a T Cell engager will be a milestone in the drug discovery using Tribody™ platform.

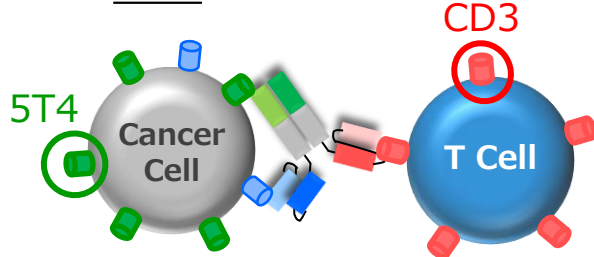
By varying combination of targets and number of binding

- 1) More effective than normal antibodies are expected
- 2) Co-administration of multiple drugs  $\Rightarrow$  single drug administration (merits such as patients' QOL, healthcare economic benefits are expected)

## CBA-1535 (currently in Phase I)

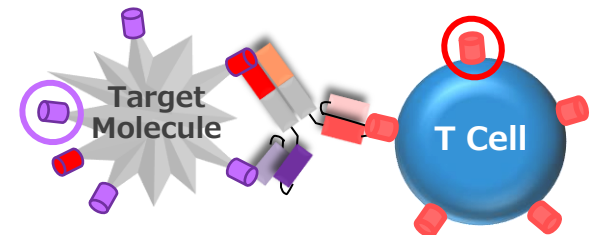


**53X**

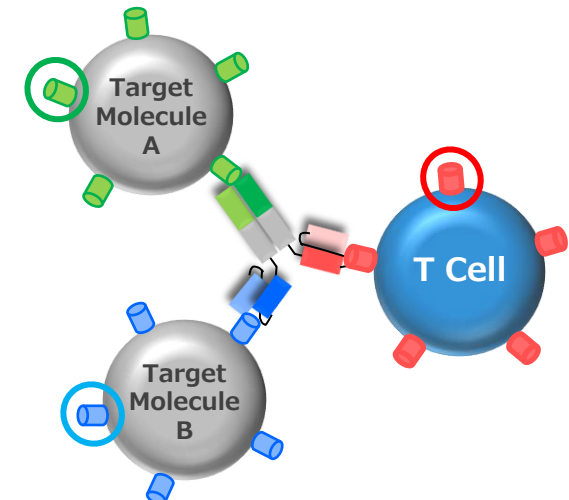


**Next generation of CBA-1535**

## Candidate for new development



**Target other than 5T4**



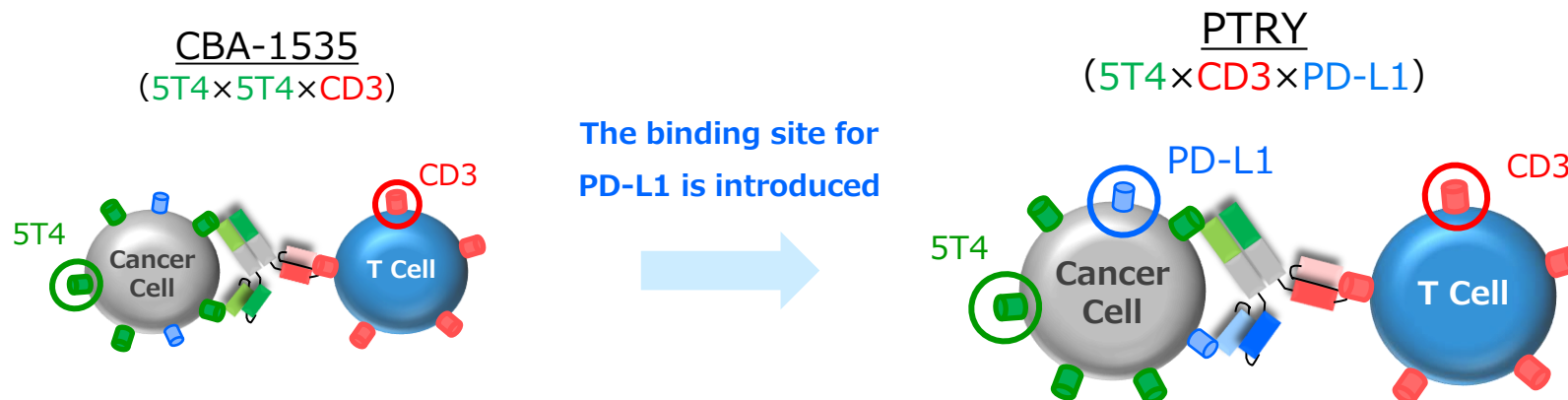
# PTRY New Pipeline



## PTRY (humanized antibody 5T4/CD3/PD-L1 multi-specific antibodies)

Target molecules : 5T4×CD3×PD-L1

<b>Origin</b>	Therapeutic antibodies for cancer treatment using Tribody™ technology consisting of three binding sites. Therapeutic antibodies for cancer treatment targeting antigen-binding sites 1) solid tumor expressing 5T4, 2) T-cell engager CD3, and 3) immune checkpoint inhibitor PD-L1.
<b>Therapeutic Area</b>	Malignant mesothelioma, small cell lung cancer, non-small cell lung cancer, Triple Negative Breast Cancer (TNBC) etc.
<b>Expectation</b>	A new study drug for patients who have not responded adequately to standard cancer immunotherapy. It is also expected to be useful in contributing to the healthcare economy by reducing drug prices.
<b>Patent</b>	Patent application completed



The results of the joint research with Ceinge Biotechnologie Avanzate (“Ceinge”) in Italy were published in an international academic journal, the Journal of Experimental & Clinical Cancer Research.

[Novel tri-specific tribodies induce strong T cell activation and anti-tumor effects in vitro and in vivo | Journal of Experimental & Clinical Cancer Research | Full Text \(biomedcentral.com\)](#)

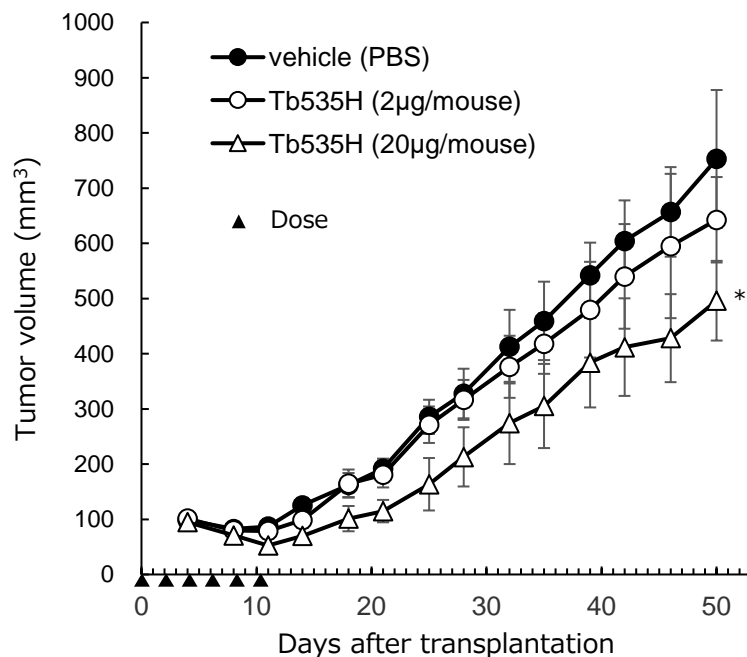
# PTRY Efficacy of the drug in vivo



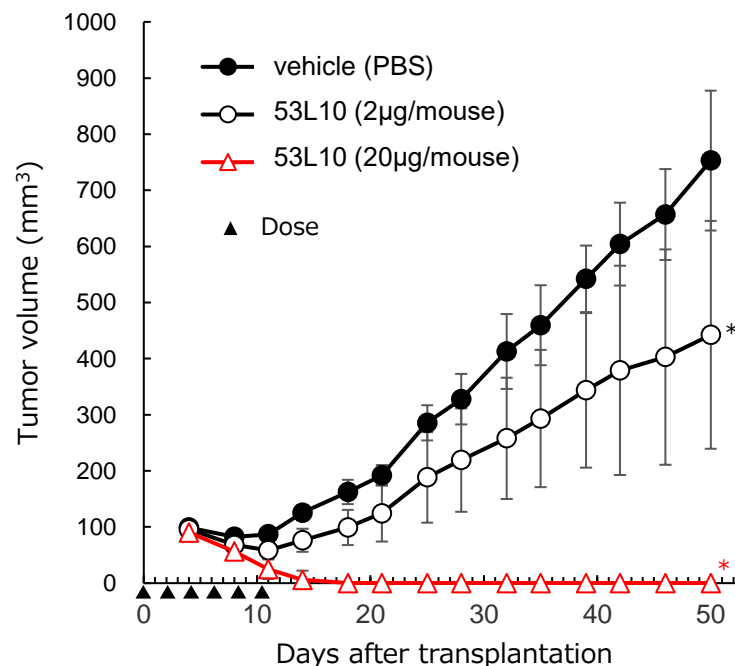
## 5T4×CD3×PD-L1 demonstrated strong anti-tumor activities

<In vivo drug efficacy data in lung cancer models> Passariello et al. *J Exp Clin Cancer Res* (2022) 41:269

Tb535H = CBA-1535  
(5T4×5T4×CD3)



53L10 = PTRY  
(5T4×CD3×PD-L1)



Focus on development and out-licensing as a next-generation pipeline of CBA-1535

## PCDC (humanized anti-CDCP1 antibody for antibody drug conjugate)

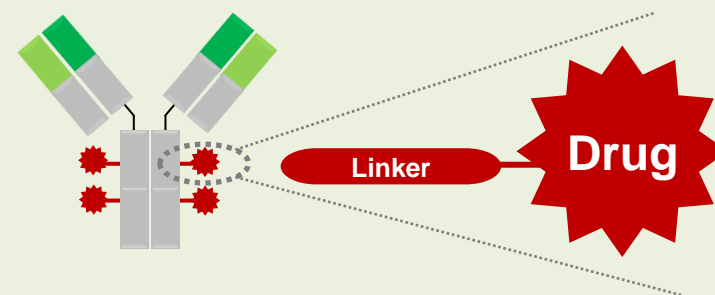
<b>Origin</b>	Humanized anti-CDCP1 antibody discovered by Chiome's proprietary antibody technologies.
<b>Therapeutic Area</b>	Solid tumors (lung, colorectal, pancreatic, breast, ovarian etc.)
<b>Expectation</b>	CDCP1 is a First-in-class therapeutic target highly expressed in broad range of solid tumors, including standard-of-care resistant cases. High efficacy and safety expected from binding and toxicological profiles of the antibody.
<b>Patent</b>	"ANTI-CDCP1 ANTIBODY" : The international patent application is filed under the PCT.

- Promoting out-licensing activities, mainly in the field of ADC
- Pharmacological data of animal model drug efficacy using amanitin has been added to out-licensing data packages.
- Progressing in contacting out-licensing candidate companies at conferences in Japan and abroad.

### Out-licensing strategy/target

1. Pharmaceutical companies wishing to expand their pipeline as ADC
2. Pharmaceutical companies already own ADC technology but are looking for antibodies for ADC

### Antibody-Drug Conjugate Technology

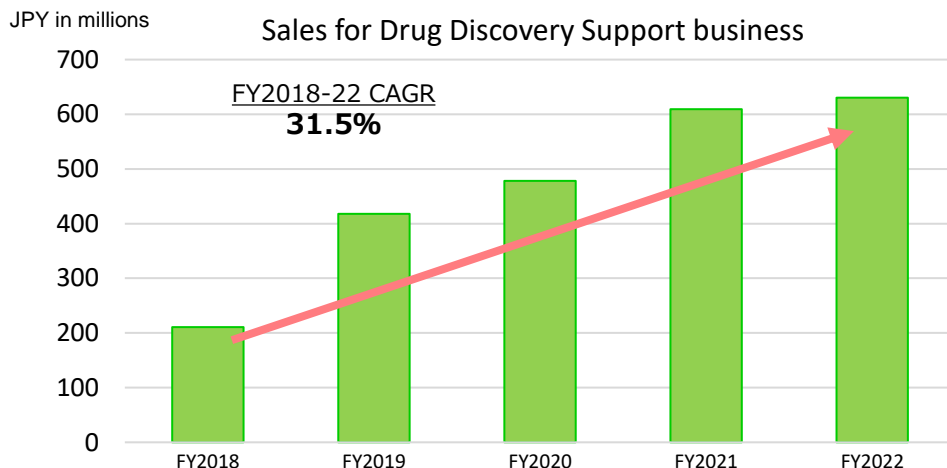


# Drug Discovery Support business



## Sales increase in contracted services

- Net sales of ¥630 million (an increase of ¥20 million year-on-year, ¥10 million increase from forecast)
- The amount of business with existing clients is steadily increasing, as domestic pharmaceutical companies highly evaluate our technical service capabilities.
- Service agreement with option contract with Rohto Pharmaceutical Co. Ltd. concluded in July 2022 on therapeutic antibody generation. In case the candidate antibody proceeds to the commercialization/development stage, an option contract will be exercised (the duration of the option agreement is for five years, starting from the completion of tasks under this agreement).
- Started dealing with domestic pharmaceutical companies and research institutions, mainly spot deals.



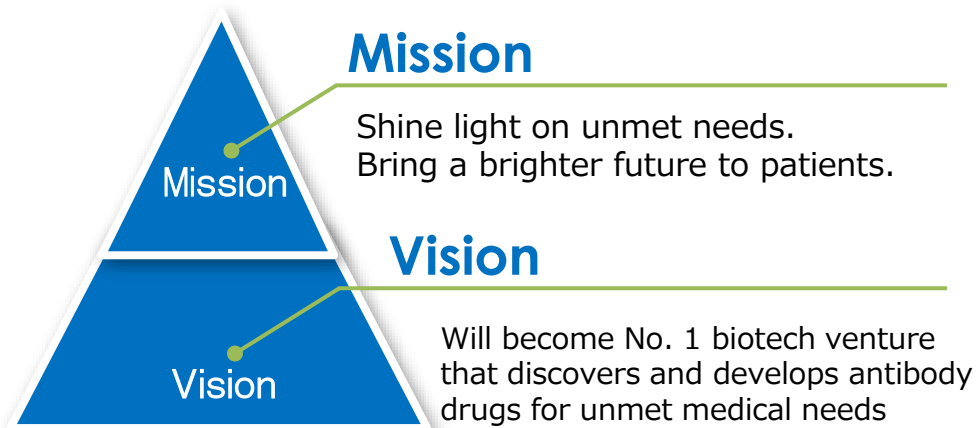
Major clients	Contract date
Chugai Pharmaceutical Co., Ltd.	Jun. 2011
Chugai Pharmabody Research Pte. Ltd	Aug. 2012
Mitsubishi Tanabe Pharma Co., Ltd. TANABE RESEARCH Laboratories U.S.A., Inc.	Dec. 2016
Ono Pharmaceutical Co., Ltd.	Oct. 2018
Kyowa Kirin Co., Ltd.	Jul. 2019



## **Appendix. Corporate information**



## Biotech company dedicating to satisfy unmet medical needs



### Management principle

- Place the highest priority on sound management and credibility and aim to become a corporation that grows with society.
- With creativity and science, develop therapeutic drugs for unmet medical needs, and contribute to the health of patients.
- Achieve successive product pipelines and improvement of corporate value through collaboration with external institutions.

- Founded:  
February 2005
- Listed on the stock exchange:  
Dec.2011  
(Tokyo Stock Exchange Growth Section)



- President and Chief Executive Officer:  
Shigeru Kobayashi, M.E.
- Location :  
<Head Office and Research Laboratories>  
3-12-1Honmachi, Shibuya-ku, Tokyo  
<Drug Discovery Laboratories>  
2-13-3 Nogawahonchou, Miyamae-ku,  
Kawasaki-city, Kanagawa
- Number of Employees :  
64 (As of Dec. 31, 2022)
- Business :  
Chiome Bioscience (4583.T), is a public company leveraging a proprietary monoclonal antibody generating technology, for drug discovery and development, as well as providing drug discovery supports.



## Drug Discovery and Development Business

This is business to obtain revenues such as upfront, milestone, and royalty payments relating to out-licensing of patents of pipeline product and drug candidates, and also, income from collaborative research. It drives our future growth.

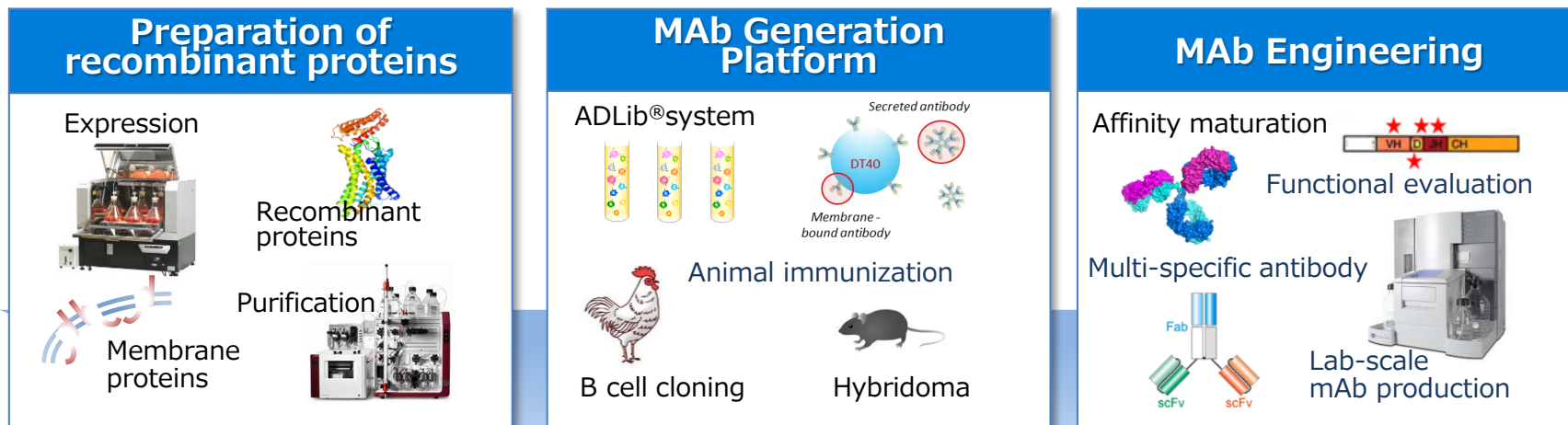
## Drug Discovery Support business

This is business to obtain revenues from antibody generation service by using platform technology that Chiome possesses to support drug discovery research at pharmaceutical companies, or for diagnostic and research purposes at academia or institutes on fee-for-service scheme. It secures constant revenue stream.

# Core competence for developing business



## Technology Platform (Chiome's mAb Discovery Engine)



Chiome possesses antibody platforms including its proprietary technology, and extensive know-hows and experiences in protein/antibody engineering to streamline the process of drug discovery.

### Advantage

Leveraging technology platforms to promote both Drug Discovery and Drug Discovery Support Businesses to Generate Sustainable Profits

### Drug Discovery and Development

Development of therapeutic drug and diagnostic agent

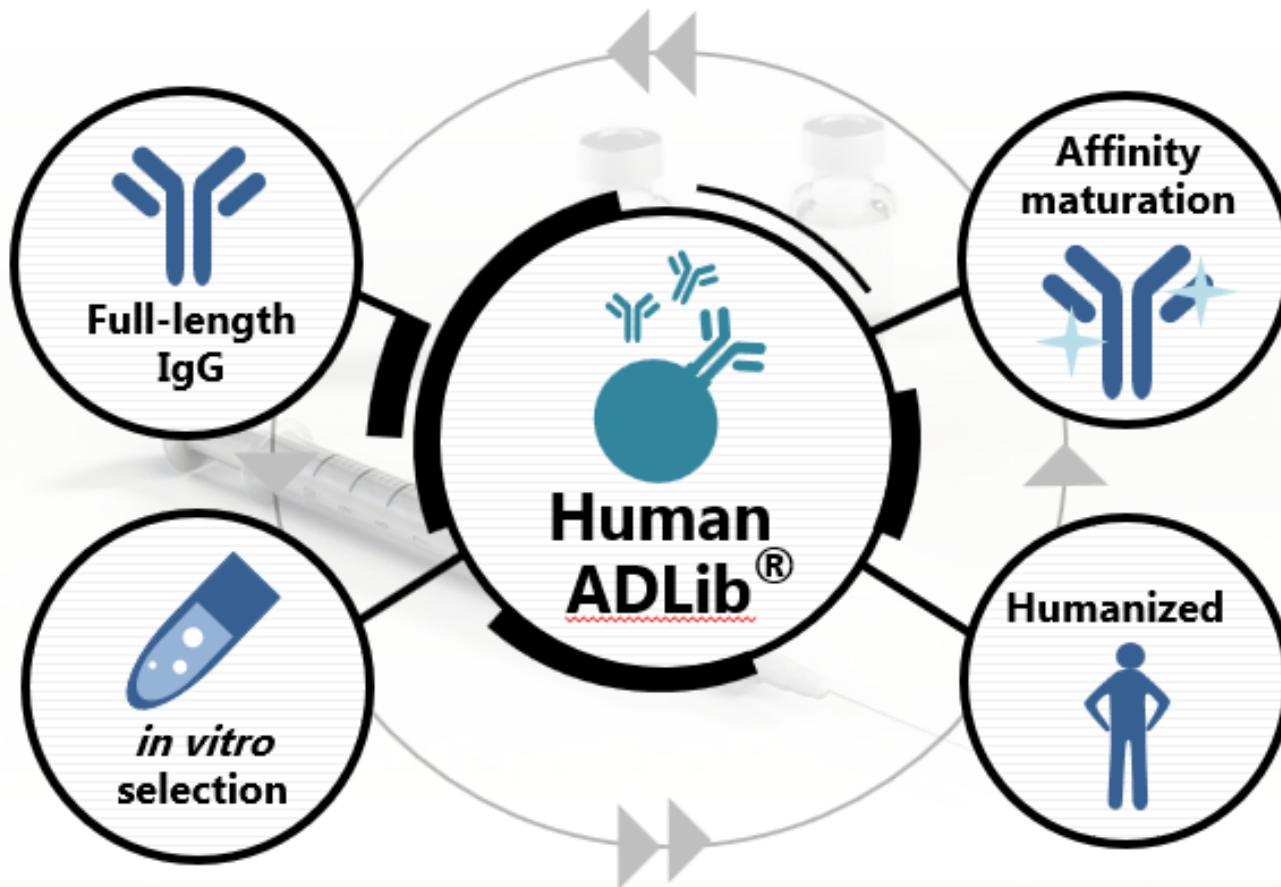
### Drug Discovery Support

Contract service for drug discovery

# Core technology : Human ADLib<sup>®</sup> System



## One-stop-order platform for antibody drug discovery

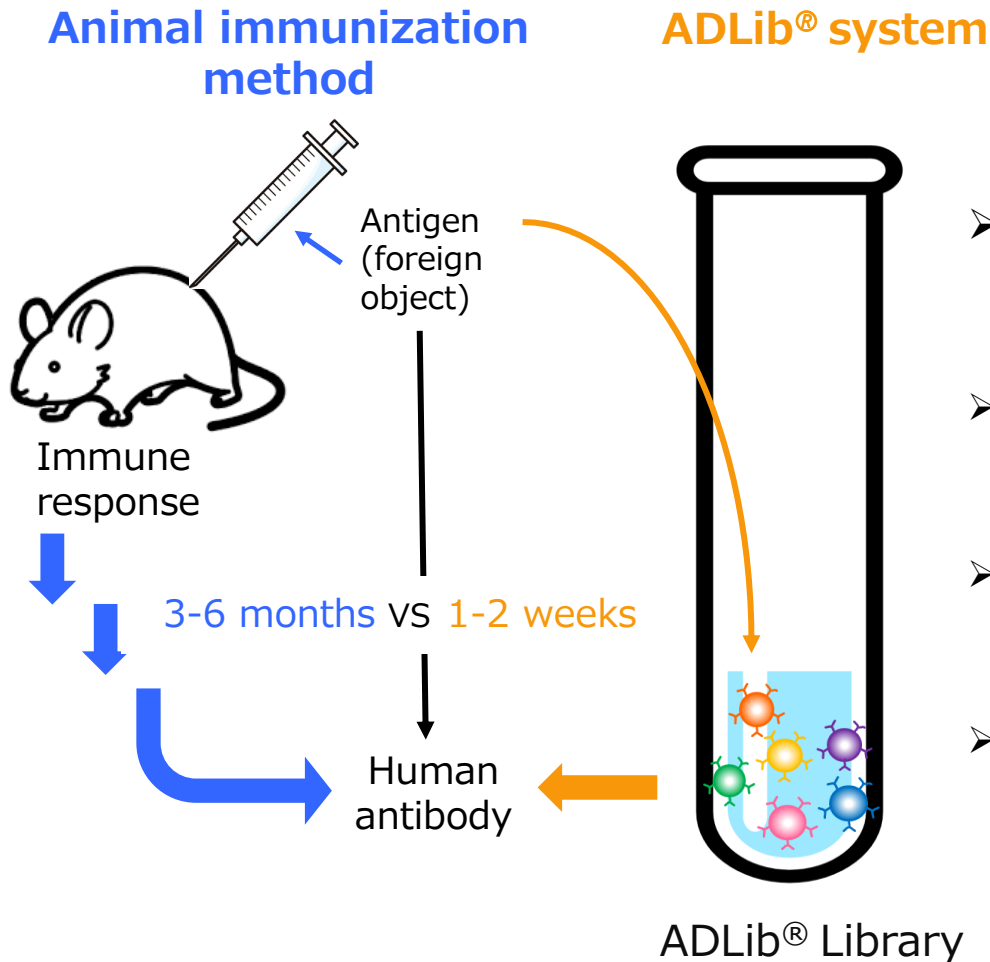


The ADLib<sup>®</sup> system offers a platform library with unique array space that adds seamless Affinity maturation function. It is a one stop order drug discovery and research tool that can complete all the steps necessary for antibody drug discovery such as selection, full-length IgG expression, humanization, and affinity maturation on 1 platform.

# Core technology that support 2 businesses: ADLib<sup>®</sup> System



Generating method of human antibodies in cultured cells (in vitro) without living organisms (animals)



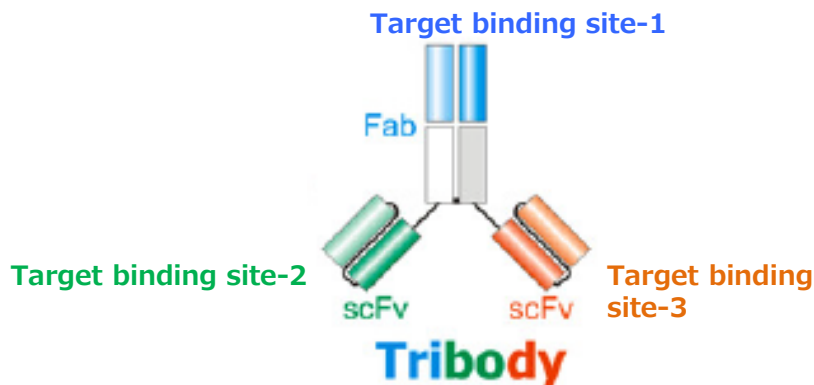
- Generate human antibodies **quicker than conventional methods**
- Unlike immunization methods using individual animals, **not affected by immune tolerance**
- By utilizing the feature of autonomous genetic diversification, **a high affinity of antibodies can be achieved in sequence**
- Acquire antibodies as early as possible leads to **early application for patents**



Technology that enables the generation of multi-specific antibodies, each molecule has three binding sites.

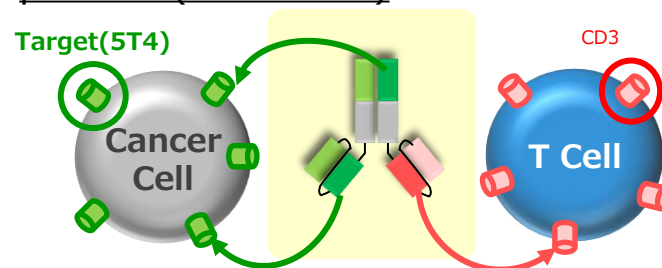
## What is Tribody™

There are three different antigen binding sites in one molecule, and this makes it possible to combine different functions.



## Example of drug candidate substance creation using Tribody™

Example of utilization in our in-house product (CBA-1535)



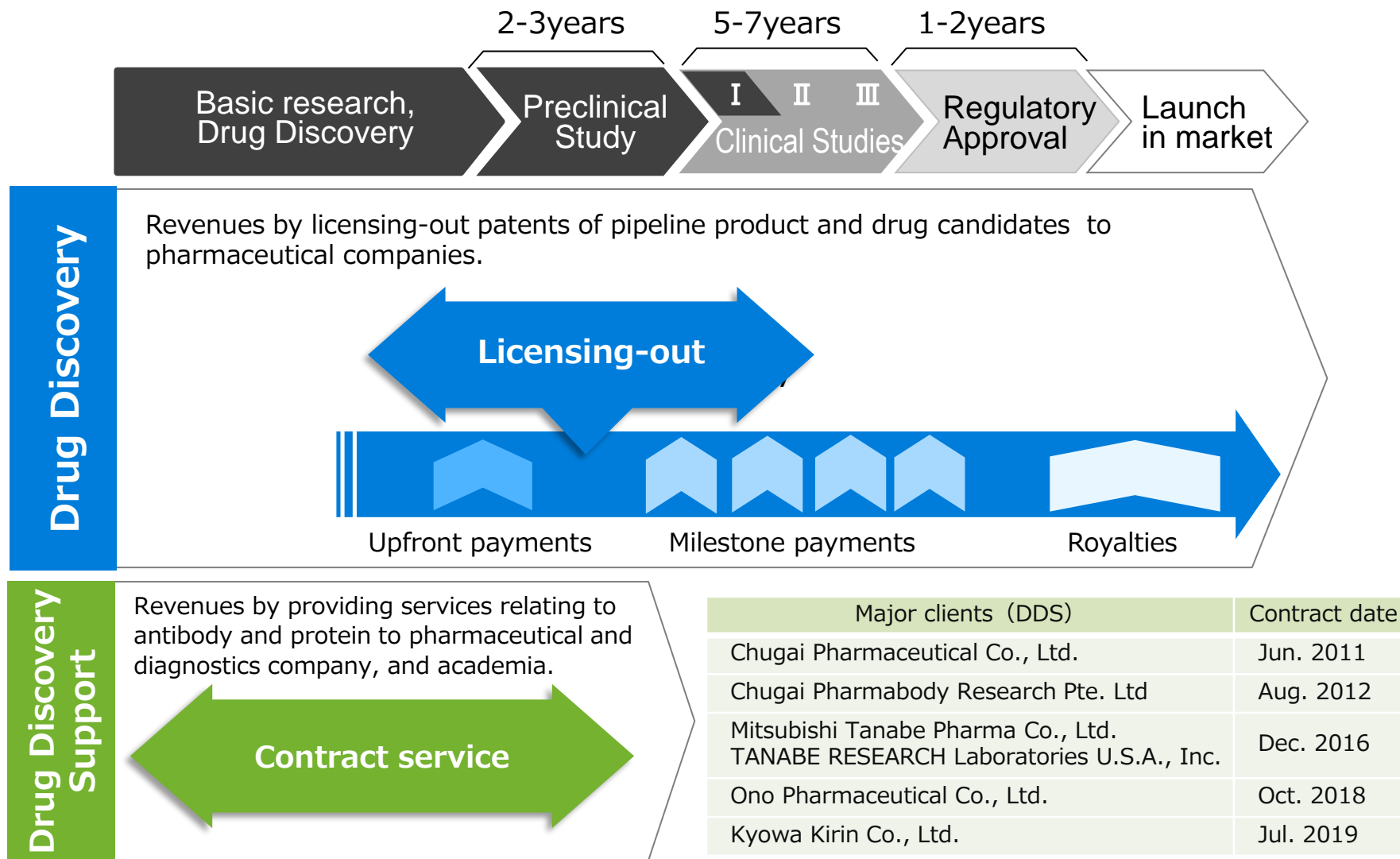
Two hands firmly hold the **target** and pull the **cancer-attacking cells** close to the cancer cell with a third hand

Various applications are possible depending on the target/binding method.

# Revenue Model



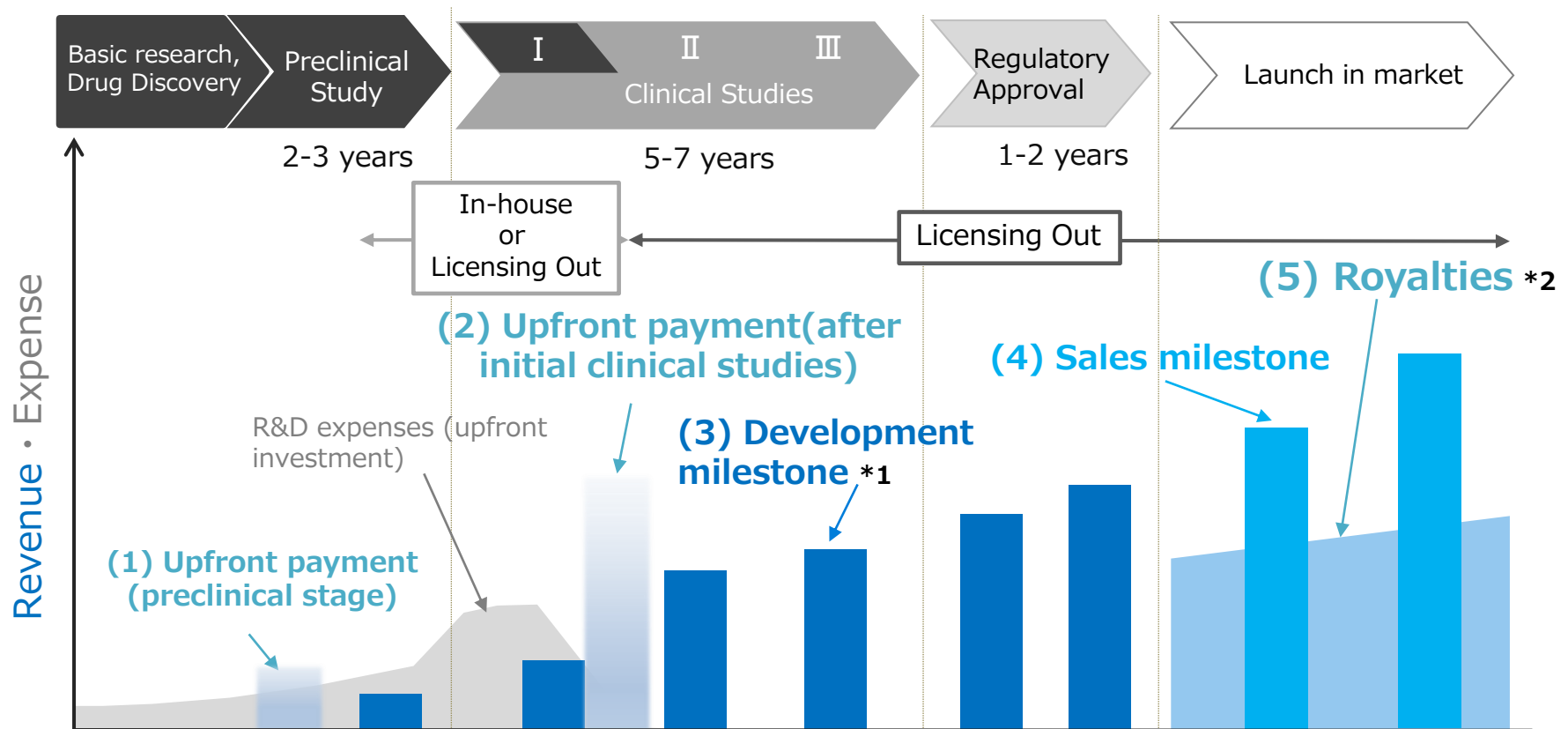
## Drug development process and Chiome's revenue model



# General image of revenue in the drug discovery business



As the stage progresses, the amount received in each milestone increases.



The above is the image of earnings to explain the Pharmaceutical Licensing Agreement. The actual agreements may vary in terms of the upfront payment, milestone stages and number/amounts of milestones, and royalty rate for each contract.

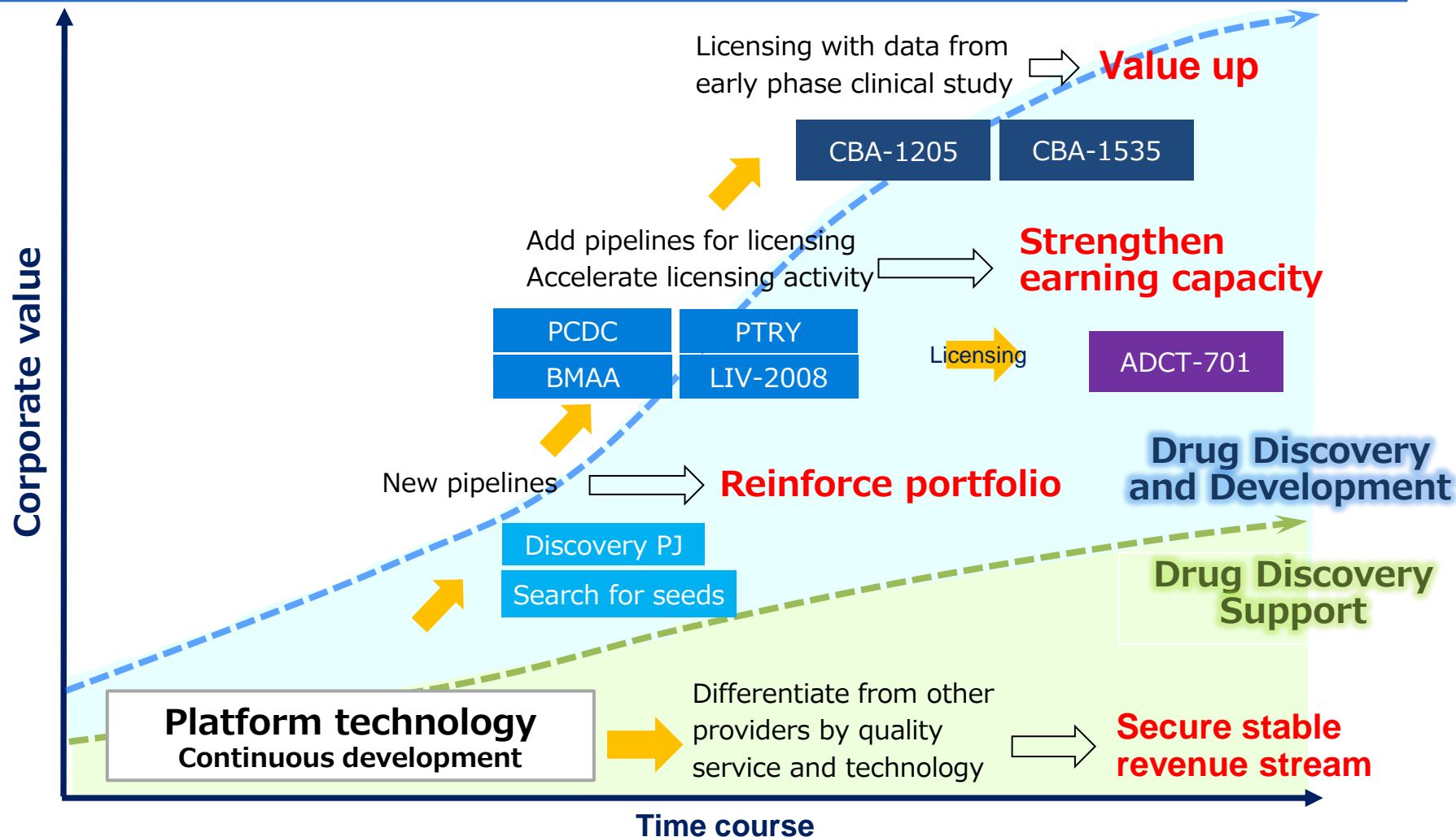
\*1 Milestone: Income received by the licensee at each milestone after out-licensing through the progress of clinical studies and others.

\*2 Royalty: Income received as a percentage of the sales amount after a product is sold (launched)

# Business strategy for the future growth



Create candidate of innovative antibody drugs for unmet medical needs and pay maximum efforts to increase the corporate value by developing and licensing highly valuable antibodies.

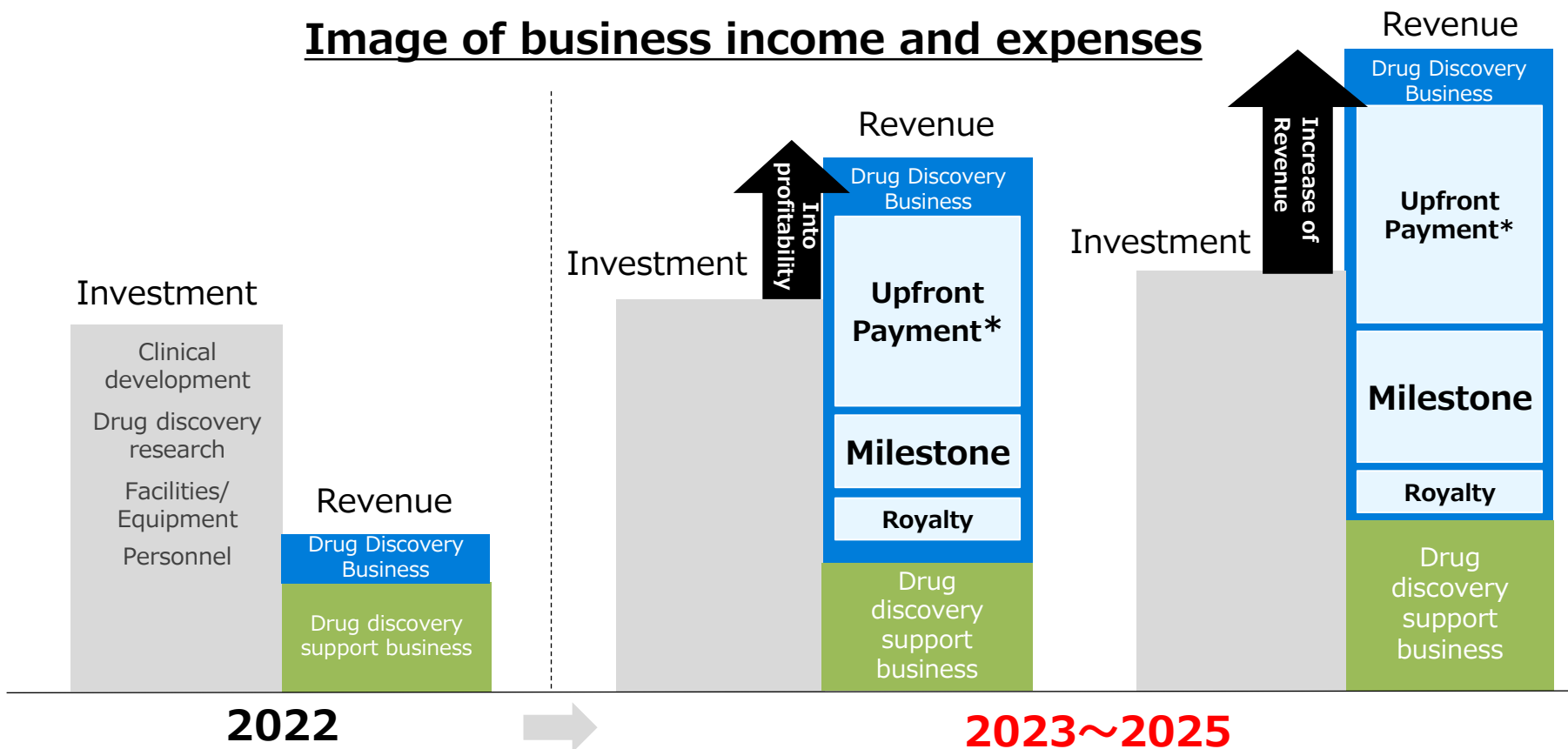


# Image of transitioning to profitability



Transition from **investment phase** to **revenue phase** by out-licensing in-house products

## Image of business income and expenses



\*On assumption of out-licensing either CBA-1205, CBA-1535 or PCDC. On assumption of out-licensing agreement with milestone income

At the time of publication of this material, the actual out-licensing agreement terms and conditions, such as licensees and various amounts, have not yet been determined. This material was created to show the profitable image of our company.



## **Appendix. Pipeline information**

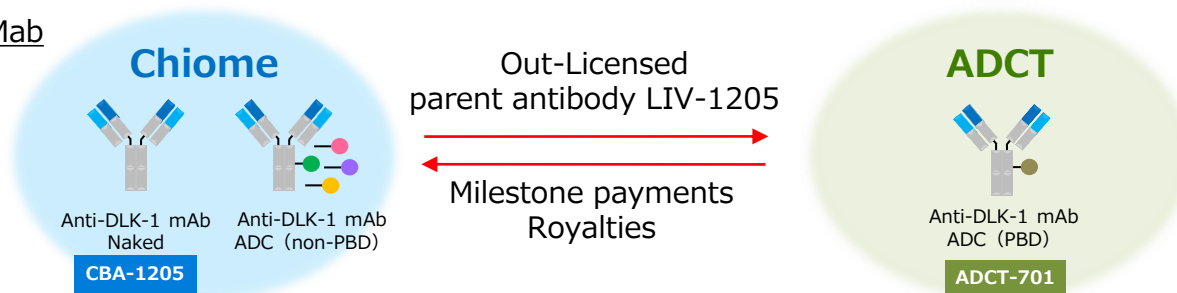
## ADCT-701\* (Humanized anti-DLK1 antibody ADC)



Therapeutic Area	Liver cancer, lung cancer, neuroblastoma etc.
Origin	An Antibody Drug Conjugate (ADC) form of LIV-1205 that was licensed out to Switzerland-based ADC Therapeutics SA in September 2017.
Patent	Granted in Japan, US, EU, China etc. (Humanized anti-DLK1 antibody )

- ADCT-701 is an antibody-drug conjugate of the antibody LIV-1205 developed by Chiome and PBD\* (\*Pyrrolobenzodiazepine : Drug with anti-tumor properties)
- ADCT is preparing for the Clinical study for ADCT-701 with National Cancer Institute (NCI) in neuroendocrine cancer.

### Rights of Anti-DLK1 Mab



Chiome has right to develop ADCs other than PBD, and it opened up the possibility of strategic development of anti-DLK-1 antibody.



## ADC Therapeutics entered into a collaboration with the National Cancer Institute (NCI) for the development of ADCT-701, targeting DLK-1.

- ADC Therapeutics and the National Cancer Institute (NCI) started a collaboration aimed at the continued development of ADCT-701, targeting DLK-1, in neuroendocrine malignancies.
- Chiome granted ADCT a worldwide exclusive license with a right to sublicense, develop, manufacture, and commercialize an ADC format of LIV-1205 and PBD conjugate.

### ADC Therapeutics Inc.

ADC Therapeutics is based in Switzerland and is focused on the development of proprietary antibody drug conjugates for the treatment of both solid and hematological cancers. ADC Therapeutics' CD19-directed ADC ZYNLONTA® is approved by the FDA, and it has multiple PBD-based ADCs in ongoing clinical studies in the US and in Europe.



### About National Cancer Institute(NCI)

The NCI is part of the National Institutes of Health (NIH) in the United States and is one of eight organizations that constitute the Department of Public Health and Human Services. NCI is involved in much of the development of anti-cancer drugs in the United States, and in addition to having a large research program within the organization, it is also actively funding cancer researchers in the United States.



## CBA-1205 (Humanized afucosylated anti-DLK1 antibody)

First in class

Origin	A humanized antibody generated by hybridoma technology in Livtech which Chiome acquired in 2015.
ADCC	GlymaxX (ProBioGen)
Therapeutic Area	Liver cancer, lung cancer, neuroblastoma etc.
Expectation	First-in-class therapeutic antibody targeting intractable cancers. Providing new therapeutics for highly malignant tumors that are without effective therapeutic drugs including hepatocellular carcinoma.
Patent	Granted in Japan, US, Europe, China etc.

### Phase I clinical study

First part: Evaluate the safety in patients

- **Enrollment completed.**
- **No serious adverse reaction reported.**
- **During the course of the study, the SD (stable disease) assessment has been carried out during the first part, and more than one and a half years of continuous dosing to a patient who was refractory to standard treatments has been confirmed.**

Second part: Evaluate the safety and efficacy of the drug in patients with hepatocellular carcinoma.

Poster presentation at the annual meeting of the American Association for Cancer Research (AACR)

Title : CBA-1205, a novel glycoengineered humanized antibody targeting DLK-1 exhibits potent anti-tumor activity in DLK-1 expressing tumor xenograft models

<https://www.abstractsonline.com/pp8/#!/6812/presentation/2425>

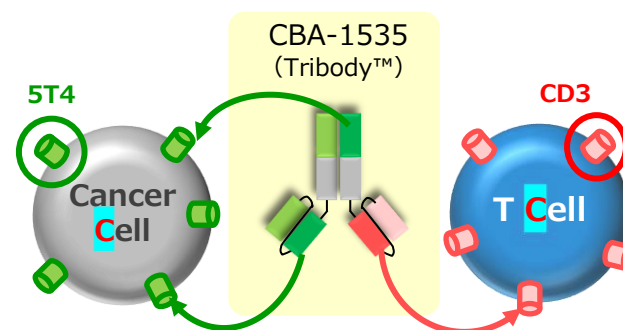
(April 2019)

## CBA-1535 (Humanized anti 5T4 & CD3 trispecific antibody)

<b>Origin</b>	CBA-1535 is a T-cell engager, trispecific antibody, directed against the 5T4 tumor antigen, a protein found on various solid tumors and is thought to be involved in metastasis.
<b>Therapeutic Area</b>	Malignant mesothelioma, small cell lung cancer, non small cell lung cancer, TNBC etc.
<b>Expectation</b>	First-in-class therapeutic antibody with trispecific format Offer a new treatment option for a disease which has poor prognosis and where there are only a few effective treatments.
<b>Patent</b>	Granted in Japan, UK, US, China. Pending in Europe etc.

Phase I study: Dosing for patients has started in the first part for safety and initial drug efficacy evaluation.

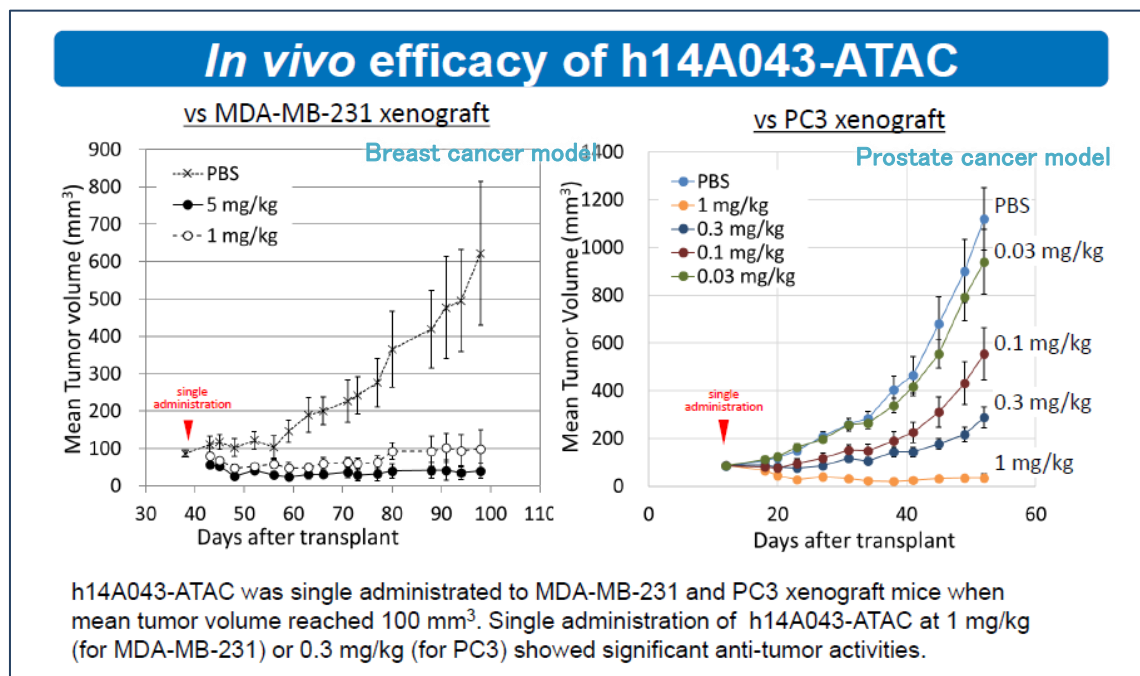
Study sites: National Cancer Center Hospital  
Shizuoka Cancer Center



## High anti-tumor activities were confirmed in PCDC and amanitin conjugated ADC antibodies

- Amanitin technology was introduced from Heidelberg Pharma, Germany. Amanitin is a toxin found in mushrooms that suppress tumor growth by inhibiting RNA Polymerase II.
- Characteristics and expectations of amanitin
  - High drug efficacy and the effect on current ADC-resistant cancer are expected
  - Heme, ocular and neurotoxicity that are observed in current ADC are low

※Heidelberg Pharma HP (<https://heidelberg-pharma.com/en/research-and-development/adc-technology>)





## BMAA (Humanized anti-Semaphorin3A antibody)

First in class

Origin	A humanized antibody generated using the ADLib® System. Demonstrated as a selective antibody possessing functional inhibitory activity through collaboration with Professor Yoshio Goshima in Yokohama City University.
Therapeutic Area	Undisclosed
Expectation	To be applied in a wide range of disease areas including inflammatory and CNS diseases which involve SEMA3A. Providing treatment methods for patients who do not respond to traditional therapeutics for diabetic retinopathy, which is the primary medical condition causing loss of sight in adulthood.
Patent	Granted in Japan, US and Europe etc.

- Completion of a research collaboration with an overseas research institute aimed at diseases involving Semaphorin 3A.
- The data obtained so far on Semaphorin 3A and the exploratory research data (Semaphorin family) will be used for future business development activities.



## LIV-2008 (Humanized anti-TROP2 antibody)

<b>Therapeutic Area</b>	Breast cancer (TNBC), lung cancer, colorectal cancer etc.
<b>Expectation</b>	LIV-2008 is a humanized monoclonal antibody targeting cell surface antigen "TROP-2" which is overexpressed in breast cancer, colon cancer, lung cancer and several types of solid cancers and is also expected to play a key role against the proliferation of cancer cells.
<b>Patent</b>	Granted in Japan, US, EU, China etc.

The license agreement with Shanghai Henlius Biotech, Inc. terminated as of January 17, 2023.

We have agreed to terminate the license agreement that we entered into with Henlius in January 2021, (granting development, manufacturing, and marketing in China, Taiwan, Hong Kong and Macau, and option rights in the rest of the world). Due to the business strategy decisions, such as the development status of similar products in the market, Henlius decided not to proceed further.

### Future plan of this antibody

We will explore new out-licensing opportunities for this antibody, together with CBA-1205, CBA-1535 and PCDC which we are actively pursuing out-licensing activities.



**Shine light on unmet needs.  
Bring a brighter future to patients.**

**To accelerate drug discovery and development of mAb  
for therapeutics to overcome current medical unmet-needs**





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