

Supplementary Information for Financial Results Q3 FY12/22

Nov. 14, 2022



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

Chiome Bioscience Inc.



- 1. Overview of Q3 FY12/22 “Financial results”**
- 2. Overview of Q3 FY12/22 “Operation highlights”**

Appendix.

Corporate information

Pipeline information



Overview of Q3 FY12/22 “Financial results”

Financial results: Profit and Loss



(JPY in millions)

	Q3 FY2021	Q3 FY2022	Increase (decrease)	Main reasons for increase / decrease
Net sales	541	433	(107)	
Drug Discovery & Development	103	0	(103)	Upfront payment of the out-licensing contract was recorded in FY12/21
Drug Discovery Support	438	433	(4)	
COS/SGA	1,392	1,473	80	
R&D Expense	860	916	56	Expenses recorded for the completion of manufacturing of study drugs for CBA-1535
Other costs	532	556	24	
Operating Loss	(850)	(1,039)	(188)	
Ordinary Loss	(843)	(1,029)	(186)	
Net Loss	(842)	(1,027)	(184)	

Financial results: Balance Sheet



(JPY in millions)

	As of Dec. 31, 2021	As of Sep. 30, 2022
Current assets	2,216	1,955
(Cash on hand in banks)	1,790	1,592
(Other current assets)	425	363 ^{*1}
Non-current assets	122	125
Total assets	2,339	2,081
Current Liabilities	392	376
Non-current liabilities	53	54
Total liabilities	446	431
Total net assets	1,893	1,650
Total liabilities and net assets	2,339	2,081

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



Overview of Q3 FY12/22 “Operation highlights”



In the dose escalation part of CBA-1205, during the course of the study, the SD (stable disease) assessments were carried out and the dose continued for more than 7 months in several patients with solid tumors.

CBA-1535, dosing to the patient in the first Phase 1 clinical study of Tribody™ started.

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

Amanitin based ADC technology was applied to anti-CD3P1 antibody (Technology introduced by Heidelberg Pharma)

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



Drug Discovery and Development – Pipeline

CBA-1205

Humanized afucosylated
anti-DLK1 antibody

- ✓ First part of Phase I clinical study, dose escalation, has been completed. Decision was made to move to the second half of Phase I study.
- ✓ The second part, dosing to patients with hepatocellular carcinoma is in progress.

CBA-1535

Humanized anti 5T4 & CD3
trisppecific antibody

- ✓ The application of the clinical study plan was submitted to the Pharmaceutical and Medical Devices Agency (PMDA) as of February 16, 2022.
- ✓ Dosing to the patients with solid tumors has started at the National Cancer Center Hospital and Shizuoka Cancer Center.

PCDC

humanized anti-CDCP1
antibody

- ✓ Promoting out-licensing activities mainly in the field of ADC applications. A data package using amanitin in ADC was also added to our out-licensing activities.

Discovery Projects

- ✓ A new patent was filed, and a paper was published on "PTRY", our new drug discovery project of Tribody™.

Pipeline - Out-Licensed programs

LIV-2008

Humanized anti-TROP2
antibody

- ✓ Henlius, which we out-licensed, considers multiple development plans for future IND applications.

ADCT-701

- ADCT and the National Cancer Institute entered a collaboration for the development of ADCT-701.
- Preparation for IND applications and clinical studies in 2022 is in progress.



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 3rd diagnostic kit developed with ADLib[®] antibodies by Fujirebio Inc.

Core Technology

ADLib[®] system Tribody[™]

- ✓ Publication of the paper
Research results on cancer immunotherapy using Tribody[™] 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[®]
<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 and improvement of ADLib[®] system). Subsidy income of 16 million yen in FY2022 in the field of infectious diseases research.
- ✓ ADLib[®] Notice of Allowance
 - Patent for a method of promoting diversification of the variable region of antibodies (Japan)
 - 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~
LIV-2008 /2008b	TROP-2	Oncology				2021.1~

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

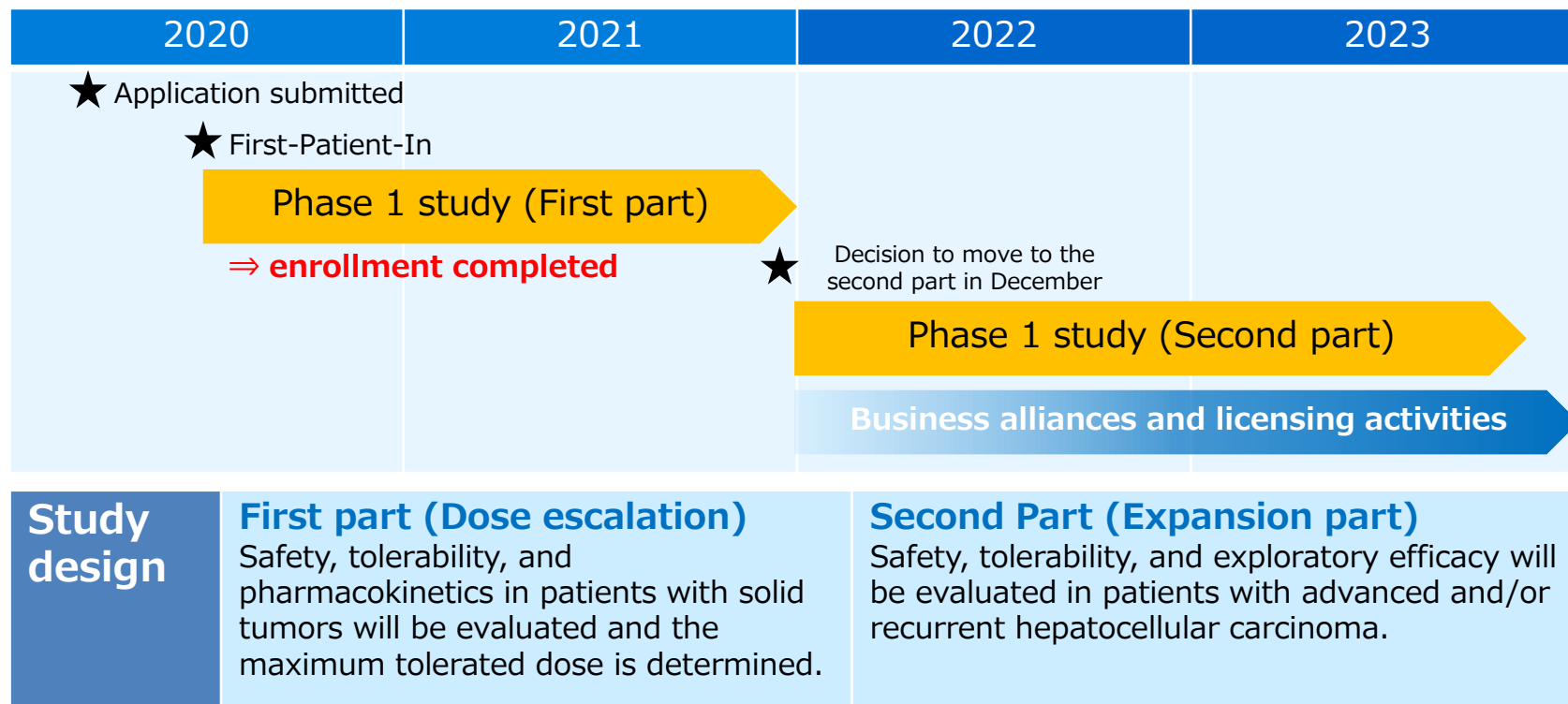
Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Status
★ PCDC	CDCP1	Oncology /ADC				Licensing opportunity
New PTRY	5T4×CD3 ×PD-L1	Oncology				Patent application completed New pipeline
★ BMAA	SEMA3A	undisclosed				Licensing opportunity
Discovery PJ/ Drug discovery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

※Completed new patent applications for the oncology project, one of the priority projects.

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**

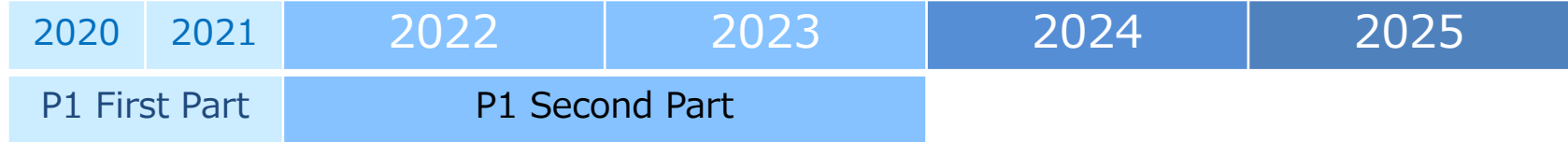


• **No serious adverse reactions reported**

• **During the course of the study, tumor assessment was carried out and the dose continued for more than 7 months in several patients who stayed in SD (stable disease) status .**

Confirmation of drug effect signal during the expansion 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



- 1st-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

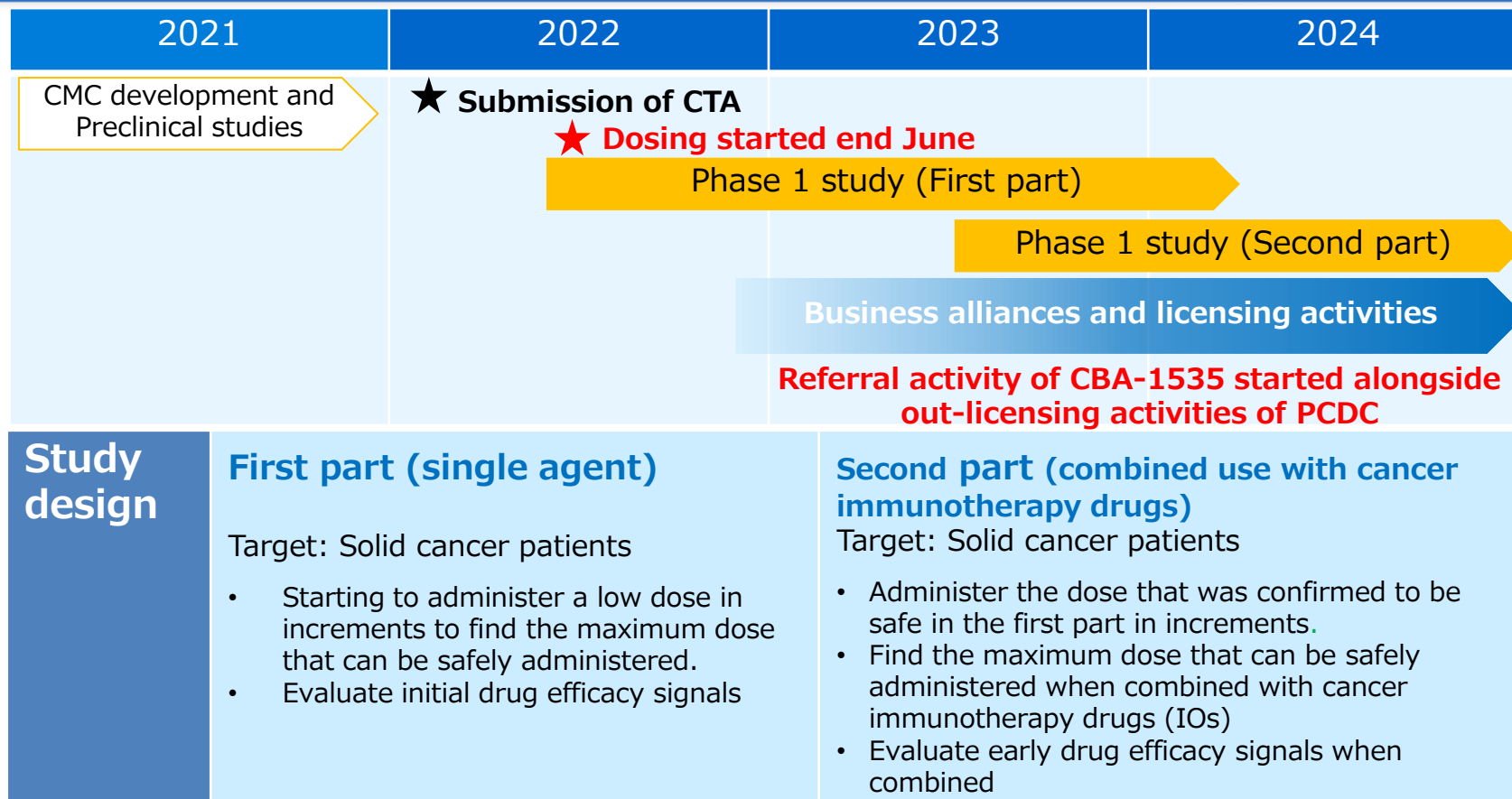
Upfront payment ≤ Upfront payment



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

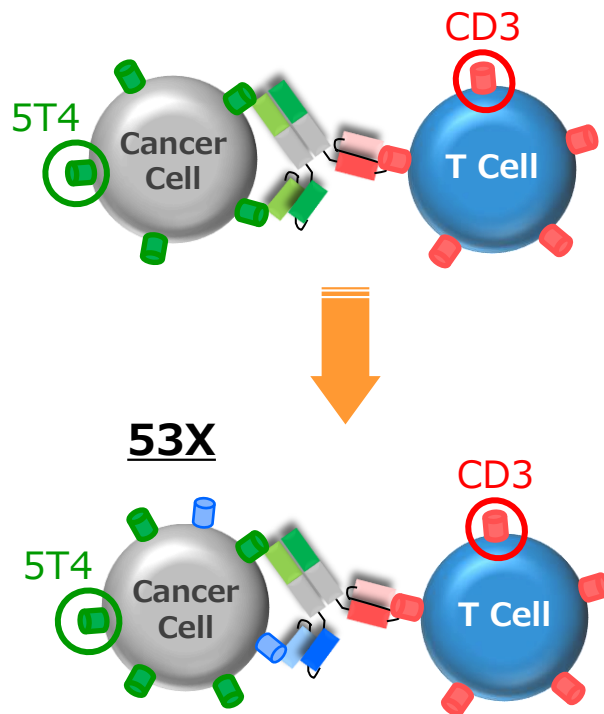
- This study is designed to confirm if CBA-1535 satisfies clinical needs such like safety and efficacy fastest by adopting combination use of IO in Phase 1
- Confirmation of safety in this study as a T Cell engager will be a milestone in the drug discovery using Tribody™ platform.



By varying combination of targets and number of binding

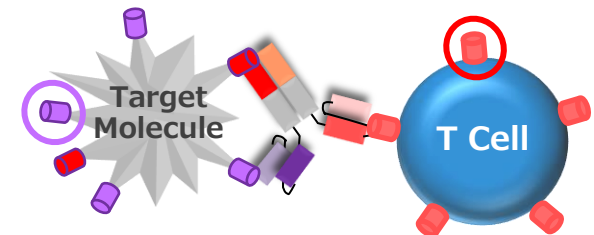
- 1) More effective than normal antibodies are expected
- 2) Co-administration of multiple drugs \Rightarrow single drug administration (merits such as patients' QOL, healthcare economic benefits are expected)

CBA-1535 (currently in Phase I)

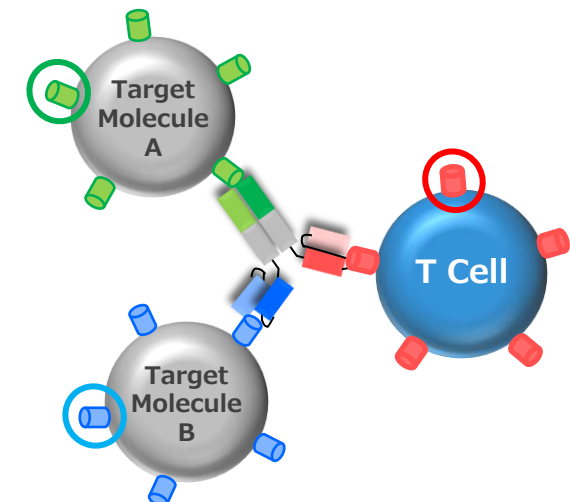


Next generation of CBA-1535

Candidate for new development



Target other than 5T4



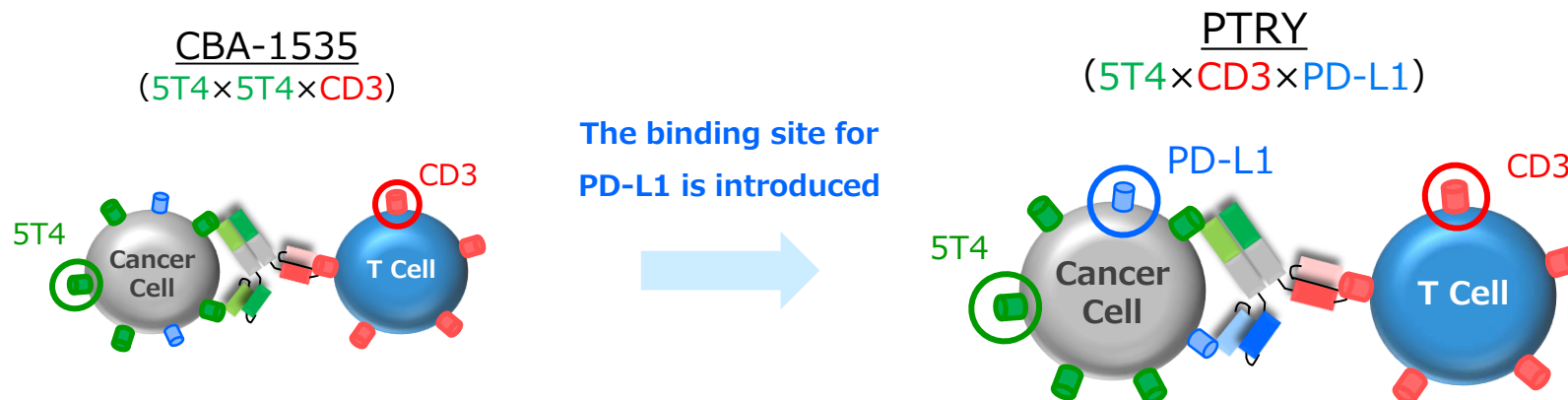
Varying combination
of targets and
number of binding



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

Target molecules : 5T4×CD3×PD-L1

Origin	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.
Therapeutic Area	Malignant mesothelioma, small cell lung cancer, non-small cell lung cancer, Triple Negative Breast Cancer (TNBC) etc.
Expectation	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.
Patent	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 \(biomedcentral.com\)](#)

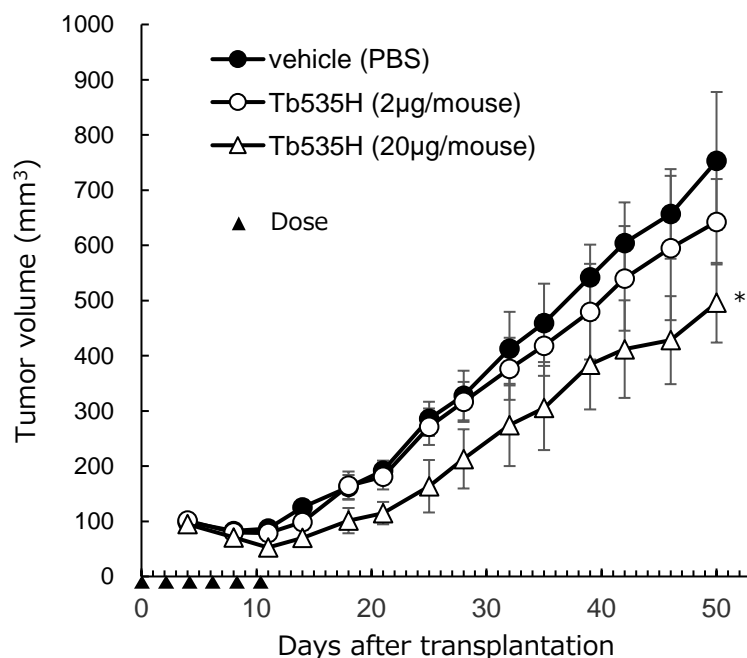


5T4×CD3×PD-L1 demonstrated strong anti-tumor activities

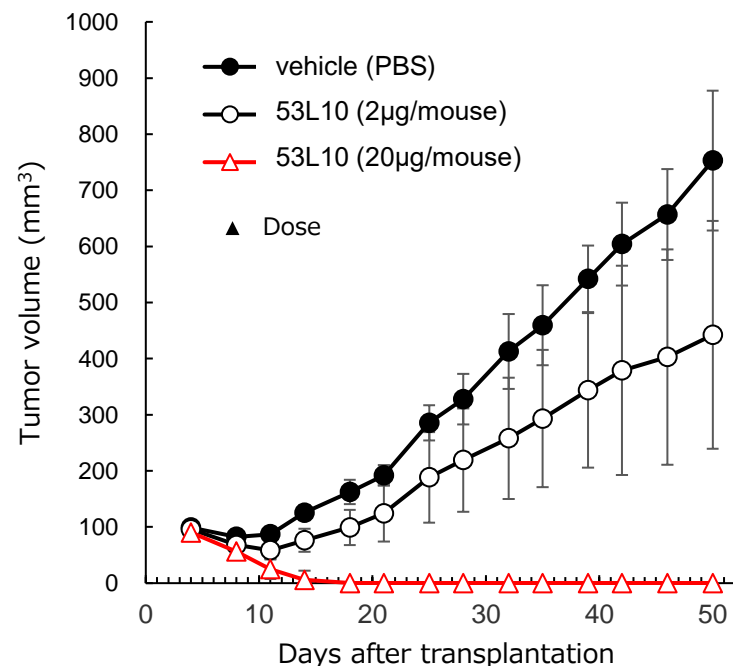
<In vivo drug efficacy data in lung cancer models>

Passariello et al. *J Exp Clin Cancer Res* (2022) 41:269

Tb535H = CBA-1535
(5T4×5T4×CD3)



53L10 = PTRY
(5T4×CD3×PD-L1)



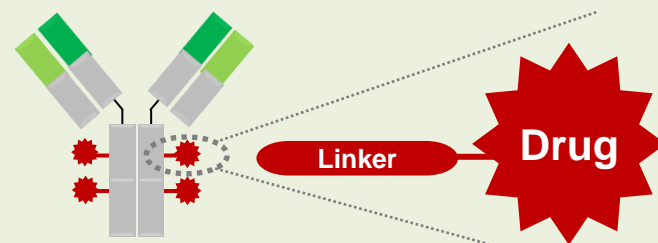
Focus on development and out-licensing as a next-generation pipeline of CBA-1535



Introducing technology: ADC with amanitin

- ✓ 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

Antibody-Drug Conjugate Technology



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

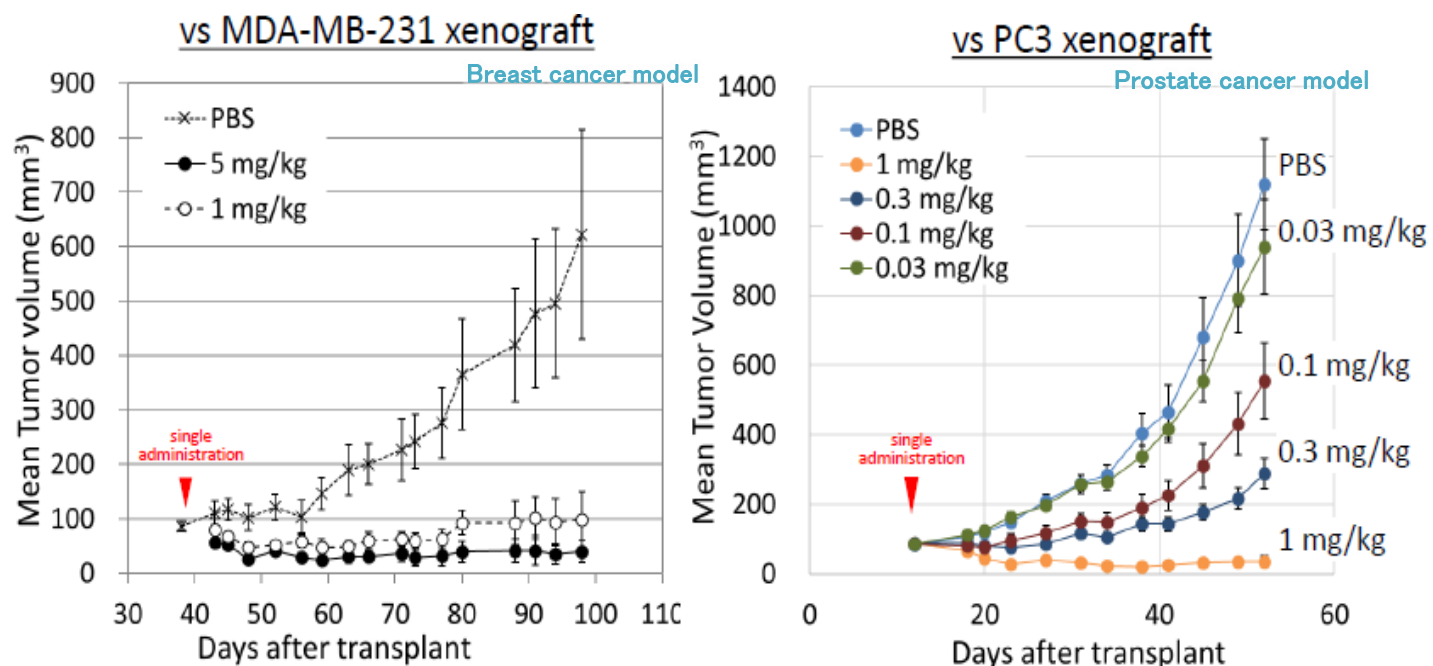
Out-licensing strategy and target clients of PCDC

1. Pharmaceutical companies wishing to expand their pipeline as ADC
 - Our company will pay license fees to Heidelberg Pharma if PCDC is determined to be out-licensed as therapeutic antibodies using amanitin
2. Pharmaceutical companies already own ADC technology but are looking for antibodies for ADC



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

In vivo efficacy of h14A043-ATAC



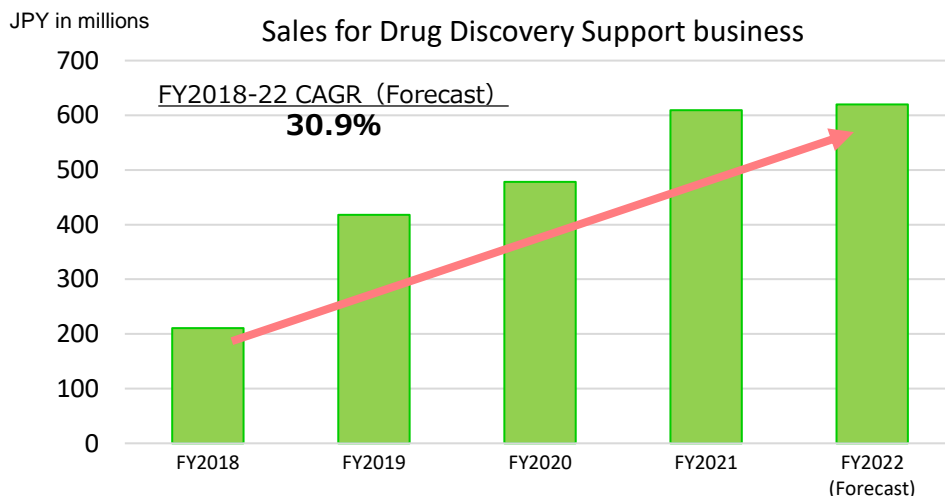
h14A043-ATAC was single administrated to MDA-MB-231 and PC3 xenograft mice when mean tumor volume reached 100 mm³. Single administration of h14A043-ATAC at 1 mg/kg (for MDA-MB-231) or 0.3 mg/kg (for PC3) showed significant anti-tumor activities.

Drug Discovery Support business



Sales increase in contracted services

- Net sales for the nine months under review were 433 million yen (a decrease of 4 million yen year-on-year)
- Despite the decrease compared to the same period last year, steady transactions with existing clients have been carried out, mainly domestic pharmaceutical companies.
- 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).



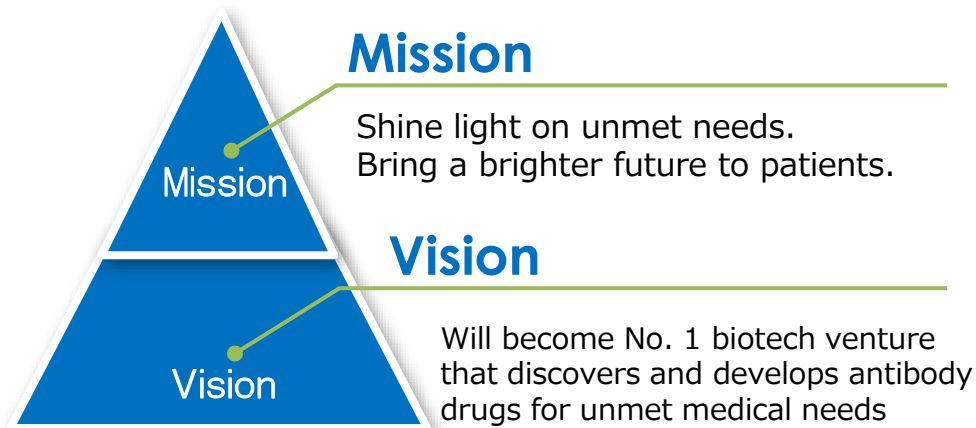
Major clients	Contract date
Chugai Pharmaceutical Co., Ltd.	Jun. 2011
Chugai Pharmabody Research Pte. Ltd	Aug. 2012
Mitsubishi Tanabe Pharma Co., Ltd. TANABE RESEARCH Laboratories U.S.A., Inc.	Dec. 2016
Ono Pharmaceutical Co., Ltd.	Oct. 2018
Kyowa Kirin Co., Ltd.	Jul. 2019



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 Sep. 30, 2022)

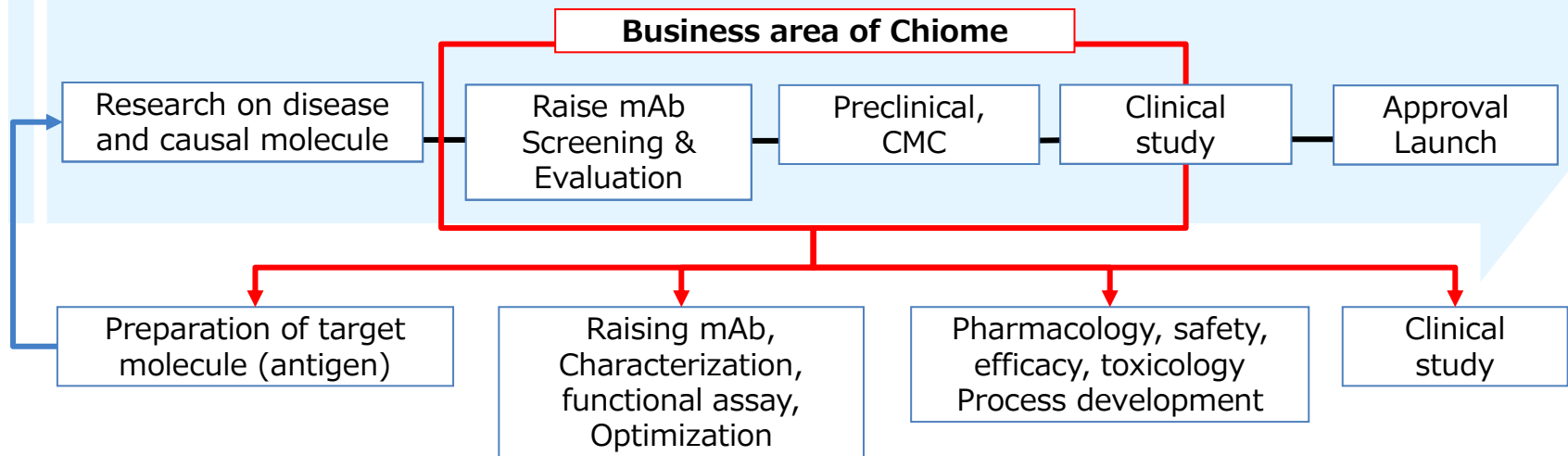
- Business :
Chiome Bioscience (4583.T), is a public company leveraging a proprietary monoclonal antibody generating technology, for drug discovery and development, as well as providing drug discovery supports.



Antibody drug discovery for diseases where high unmet medical needs exist

- Intractable diseases for which effective treatment is not available
- Diseases for which some treatments are available, but not a drug
- Effective drugs are available, but are not easy to use or accompanies with hard side effects
- Difficult for a big pharma to focus on due to small number of patient

Process of drug discovery



Groups responsible for the roles above

Protein Group

Antibody Discovery

Antibody Discovery
Labs.

Clinical
Development



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.

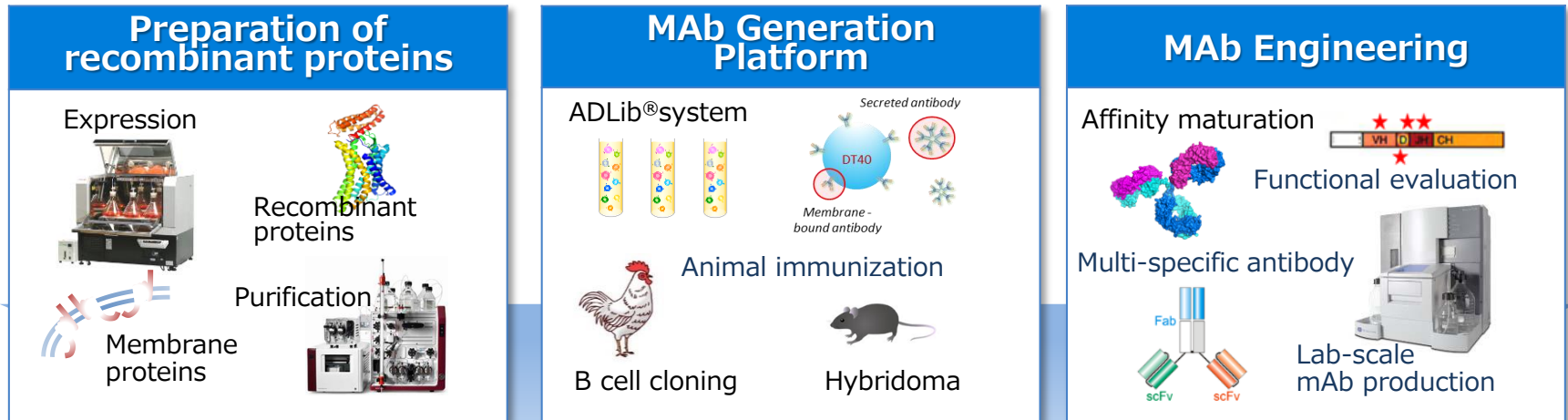
Drug Discovery Support business

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

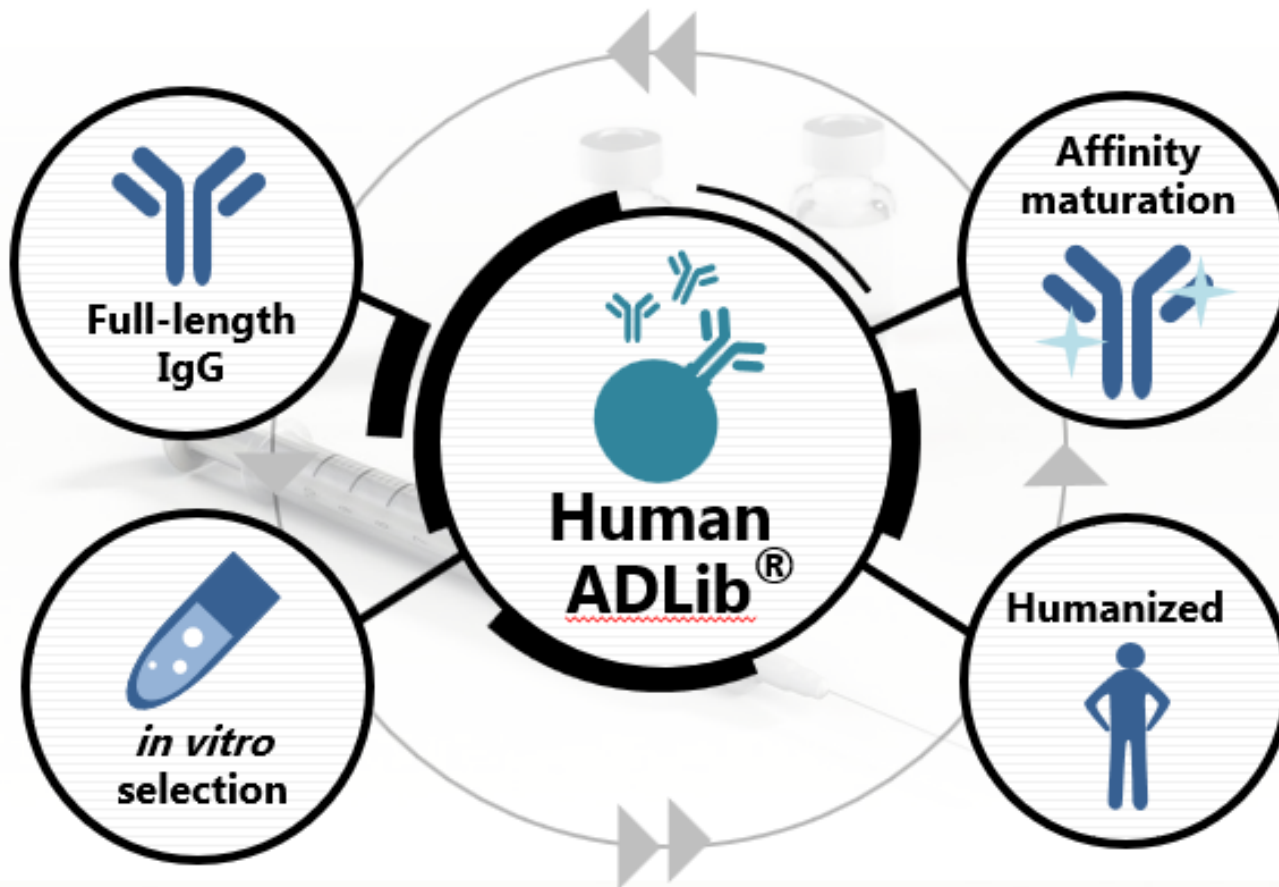
Drug Discovery Support

Contract service for drug discovery

Core technology : Human ADLib[®]System



One-stop-order platform for antibody drug discovery

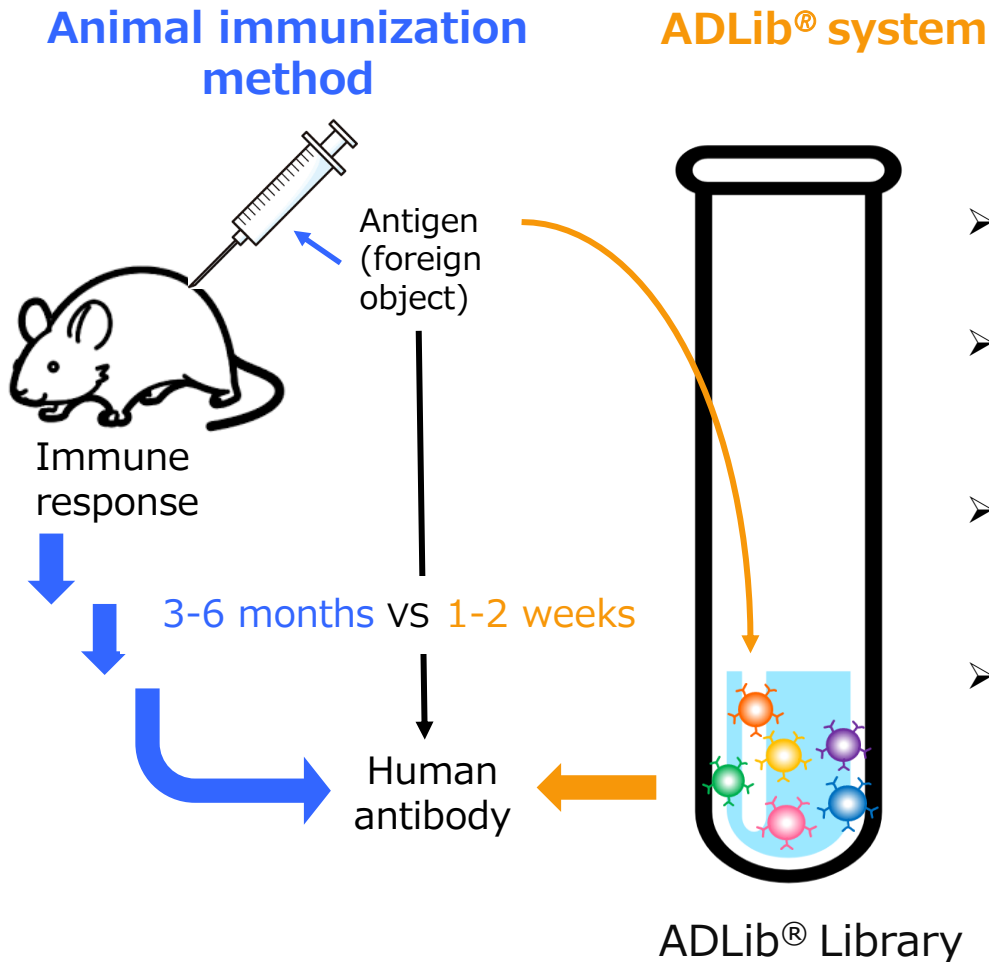


The ADLib[®]system offers a platform library with unique array space that adds seamless Affinity maturation function. It is a one stop order drug discovery and research tool that can complete all the steps necessary for antibody drug discovery such as selection, full-length IgG expression, humanization,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

Core technology that support 2 businesses: ADLib[®] System



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

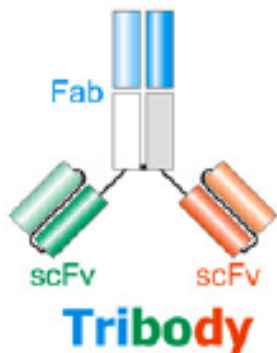


- Acquire human antibodies in a short period of time
- Unlike immunization methods using individual animals, not affected by immune tolerance
- By utilizing the feature of autonomous genetic diversification, a high affinity of antibodies can be achieved in sequence
- Acquire antibodies as early as possible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

Core technology : Tribody™



Tribody™

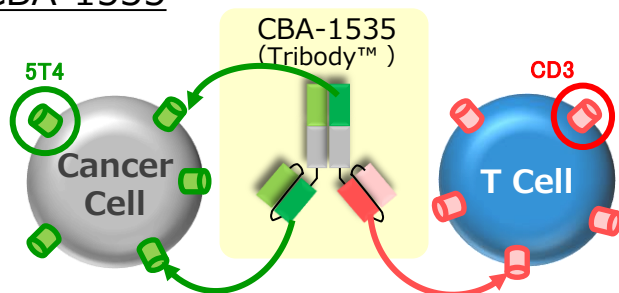


The Tribody™ technology enables the generation of multi-specific antibody products. This unique technology overcomes the key shortcomings of conventional mono- as well as of currently developed bi-specific antibody formats.



[Discover drug candidates utilizing Tribody™ technology](#)

CBA-1535



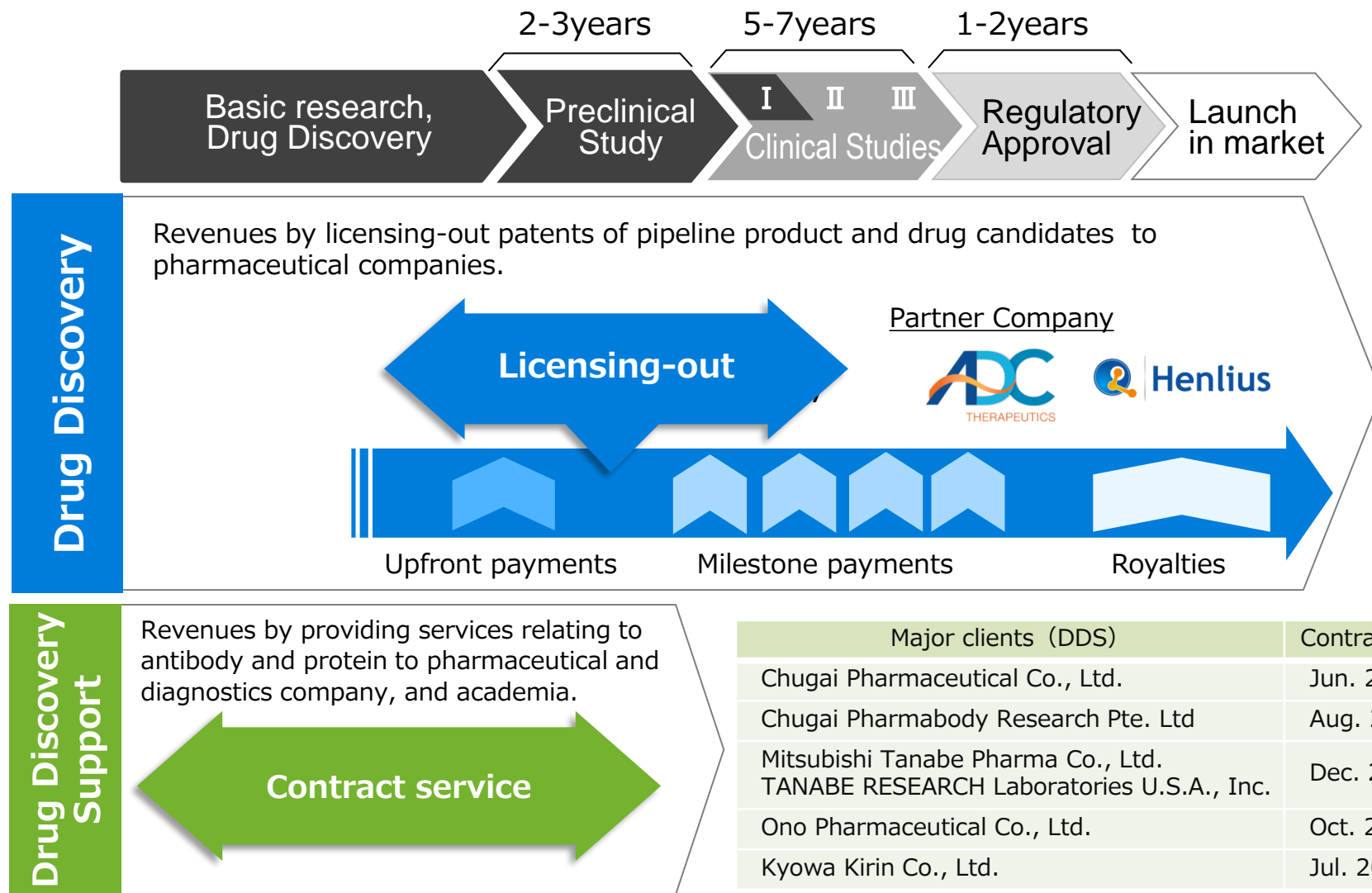
One of the binding sites can be designed to recruit immune cells (effector cells) with cytotoxic activity, such as T cells and NK cells, and the remaining 2 sites can be designed to bind to different epitopes of a cancer-specific antigen or to recognize different antigens expressed on the cancer cell surface.

By combining targets and the number of binding,
it is expected to generate antibodies to targets that could not be made into drugs in the past, and that have characteristics that will free patients from the need to administer multiple drugs in combination.

Revenue Model



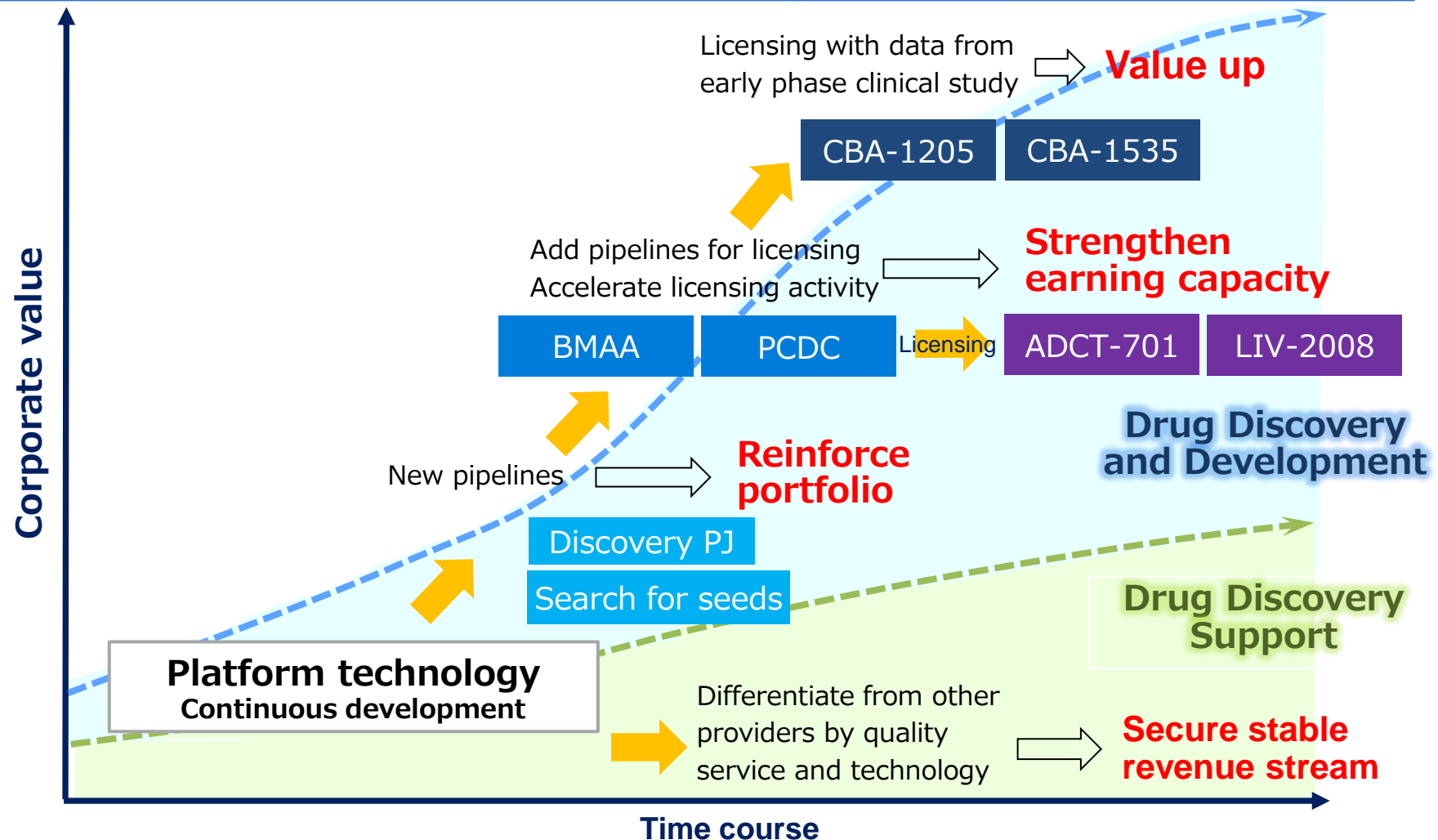
Drug development process and Chiome's revenue model



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.





Appendix. Pipeline information

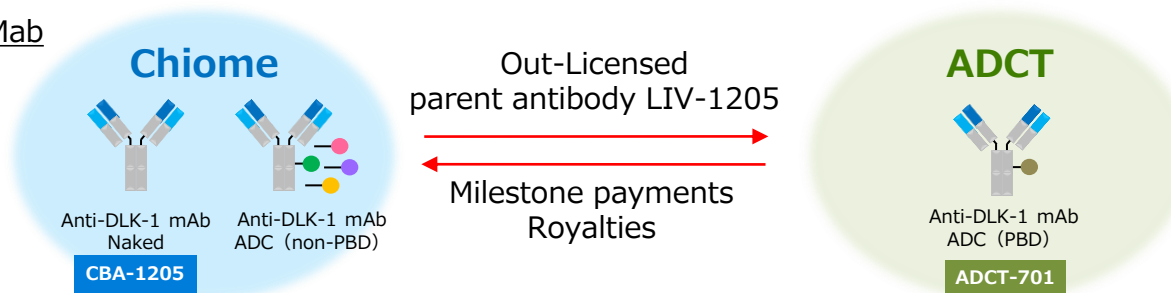
ADCT-701* (Humanized anti-DLK1 antibody ADC)



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.



LIV-2008 (Humanized anti-TROP2 antibody)



Therapeutic Area	Breast cancer (TNBC), lung cancer, colorectal cancer etc.
Expectation	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.
Patent	Granted in Japan, US, EU, China etc.

- ✓ Chiome grants an exclusive license, with sublicensing rights, to Henlius for development, manufacturing and marketing of LIV-2008/2008b and its derivatives in China (including Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan region)
- ✓ Chiome also grants to Henlius an option right to develop, manufacture and sale in the rest of the world other than the initial territory.

(Henlius Company website : [HKEX-EPS_20210114_9583899_0.PDF \(windows.net\)](#))

Conditions

Upon exercise of the above option rights to develop, manufacture and market the product on a worldwide basis, there is an agreement for a total of up to approximately US\$122.5 million in upfront payments and milestone payments based on progress in development and sales. In addition, royalty income at a fixed rate based on the sales value will be paid if the product is launched.



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) evaluations were carried out and the dose continued for more than 7 months for several patients who were refractory to standard treatments.

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

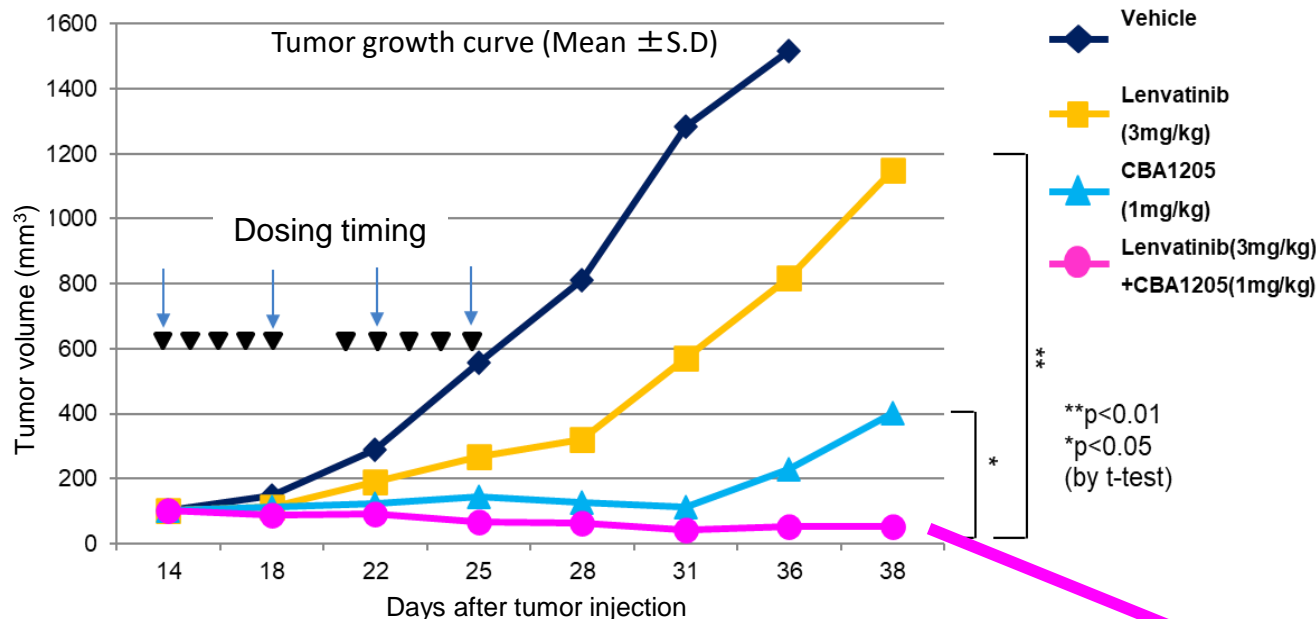
<https://www.abstractsonline.com/pp8/#!/6812/presentation/2425>

(April 2019)

A patent application, "Combination of CBA-1205 and Lenvatinib" filed in 2019 is published

Mouse xenograft study: Hep3B hepatoma model CBA-1205 + Lenvatinib

Patent: WO/2020/204033



Dosing regimen

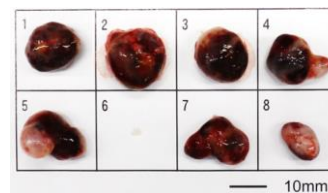
CBA-1205 : i.p., twice a week x 2 weeks

Lenvatinib: p.o., daily x 5 days a week for 2 weeks

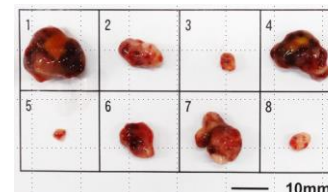
Remarkable tumor regression was observed in combination of CBA-1205 and Lenvatinib in HCC xenograft treatment model.

Tumors on Day 38

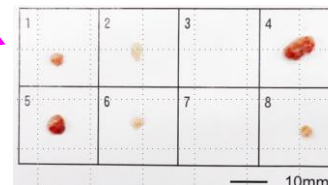
Lenvatinib (3 mpk)



CBA-1205 (1 mpk)



LEN (3 mpk) + CBA-1205 (1 mpk)

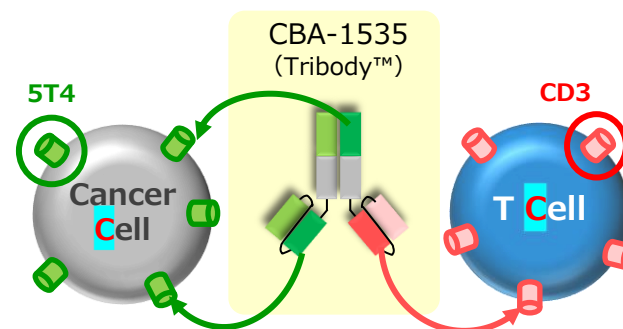


CBA-1535 (Humanized anti 5T4 & CD3 trispecific antibody)

Origin	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.
Therapeutic Area	Malignant mesothelioma, small cell lung cancer, non small cell lung cancer, TNBC etc.
Expectation	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.
Patent	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





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.

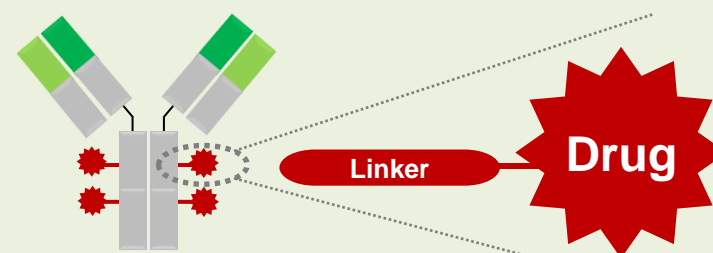
- ✓ Completion of a research collaboration with an overseas research institute aimed at diseases involving Semaphorin 3A.
- ✓ The data obtained so far on Semaphorin 3A and the exploratory research data (Semaphorin family) will be used for future business development activities.

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

Origin	Humanized anti-CDCP1 antibody discovered by Chiome's proprietary antibody technologies.
Therapeutic Area	Solid tumors (lung, colorectal, pancreatic, breast, ovarian etc.)
Expectation	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.
Patent	"ANTI-CDCP1 ANTIBODY" : The international patent application is filed under the PCT.

- ✓ Promoting out-licensing activities, mainly in the field of ADC
- ✓ 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
- ✓ Pharmacological data of animal model drug efficacy using amanitin from Heidelberg Pharma has been added to out-licensing data packages and out-licensing activities are in full speed.

Antibody-Drug Conjugate Technology





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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