Supplement Documents for Financial Results Q3 FY12/21

Nov. 12, 2021

Chiome

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

Chiome Bioscience Inc.

Agenda

1．Overview of Q3 FY12/21 “Financial results”

2．Overview of Q3 FY12/21 “Operation highlights”

Appendix.

Corporate information

Pipeline information

Overview of
Q3 FY12/21 “Financial results”

Financial results: Profit and Loss

(JPY in millions)

	Q3 FY2020	Q3 FY2021	Increase (decrease)	
Net sales	312	541	229	
Drug Discovery & Development	2	103	100	• Upfront payment of the License Agreement with Shanghai Henlius Biotech, Inc. for LIV-2008/2008b
Drug Discovery Support	309	438	128	• Growth in business with domestic pharmaceutical companies
COS/SGA	1,392	1,392	0	
R&D Expense	951	860	(90)	• Cost of the study drug manufacturing in CBA-1535 program
Other costs	441	532	90	• Up in material costs due to increased business transactions
Operating Loss	(1,080)	(850)	229	
Ordinary Loss	(1,087)	(843)	244	
Net Loss	(1,087)	(842)	245	

Financial results: Balance Sheet

(JPY in millions)

	As of Dec. 31, 2020	As of Sep. 30, 2021
Current assets	3,248	2,675
(Cash on hand in banks)	2,686	2,071
(Other current assets)	562	604
Non-current assets	246	274
Total assets	3,494	2,950
Current Liabilities	342	468
Non-current liabilities	41	53
Total liabilities	384	522
Total net assets	3,109	2,428
Total liabilities and net assets	3,494	2,950

Overview of
Q3 FY12/21 “Operation highlights”

Business Segment

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.

Operation highlights

Drug Discovery and Development – Pipeline

CBA-1205 Humanized afucosylated anti-DLK1 antibody	• Dose escalation part of Phase I Study to see safety is on-going well on track at National Cancer Center Hospital. • Expect moving to Part 2 in HCC patients at the end of 2021 or the first half of 2022.
CBA-1535 Humanized anti 5T4/WAIF1 antibody, multi-specific antibody	• Preparation work for a clinical study progresses as scheduled. • The possibility of conducting Phase 1 study in Japan where COVID-19 gives less impact on development has been discussed. Upon a consultation with the PMDA, regulatory authority in Japan, we are convinced that we can submit an application with the existing data package in the first half of 2022. • Patent granted in China as Tribody™ antibody.
BMAA Humanized anti-Semphorin3A antibody	• Began a new collaborative research with overseas research institution targeting a disease associated with Semaphorin 3A.
PCDC Humanized anti-CDCP1 antibody	• Initiate licensing work for ADC purpose in parallel with basic research. • A patent application has been published in July 2021.
Discovery PJ	• Examined the progress of research projects and research data extensively to determine the direction of each project including licensing, termination, and setting up a new project. • Preparing for filing a patent application for a new drug discovery project.

Operation highlights

Pipeline - Out-Licensed programs

LIV-2008 Humanized anti-TROP2 antibody	• License agreement with Henlius for development, manufacturing and marketing of LIV-2008/2008b and its derivatives in China is signed in January 2021. • Ongoing implementation for the evaluations at multiple overseas pharmaceutical companies.
ADCT-701	• ADCT and the National Cancer Institute entered a collaboration for the development of ADCT-701. • Preparation for IND applications and clinical trials in 2022 is in progress.

Drug Discovery Support Business

Deals with pharmaceutical companies	• Growth of business with key clients in Japan. • Extension of contract with Chugai in Japan and Chugai Pharmabody Research in Singapore (Oct. 18, Nov. 1)

Core Technology

ADLib® system	• Participate in the Grant Program of the Japan Agency for Medical Research and Development (AMED) • Patent for Human ADLib® granted in EU, and patent for antibody generation method in ADLib® granted in JAPAN. • Tokyo Medical and Dental University announces research results for Alzheimer's disease using anti-HMGB1 antibody generated by human ADLib® system.

Drug Discovery and Development -Pipeline

Out-Licensed Product

Code	Target	Therapeutic Area	Basic research, Drug Discovery / Preclinical Study / Clinical Trials	Partner
ADCT-701 (LIV-1205 ADC)	DLK-1	Oncology /ADC		ADC THERAPEUTICS
LIV-2008 /2008b	TROP-2	Oncology		Henlius

Pipelines

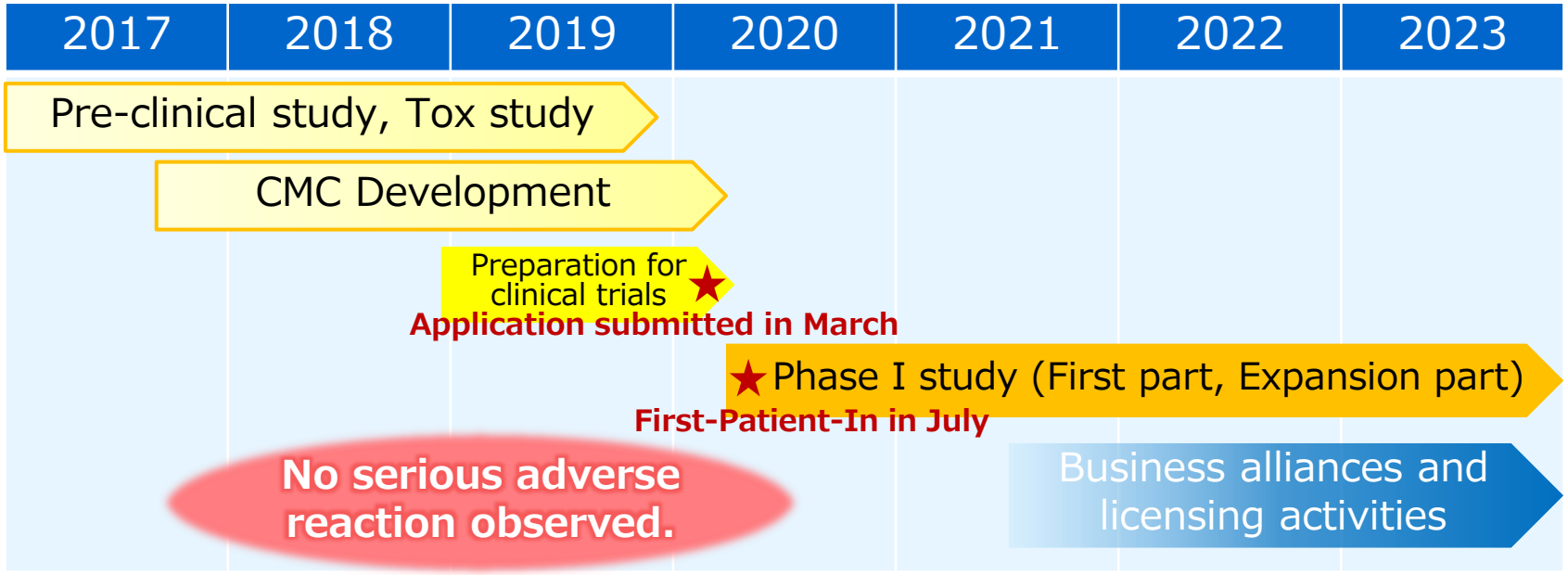
★ First in class

Project	Target	Therapeutic Area	Basic research, Drug Discovery / Preclinical Study / Clinical Trials	Status
★CBA-1205 (ADCC enhanced)	DLK-1	Oncology		Phase 1
CBA-1535 (Tribody™)	5T4×CD3 ×5T4	Oncology		Preparing for Phase 1
★BMAA	SEMA3A	undisclosed		Licensing opportunity
★PCDC	CDCP1	Oncology /ADC		Licensing opportunity
Discovery PJ (5)	Undisclosed	Oncology infectious/ rare diseases		–

As of Aug,13 2021

Drug Discovery and Development -Pipeline

Phase I study of CBA-1205 is on-going well on track.
Expect moving to Expansion part in HCC patients at the end of 2021 to the first half of 2022.



Study design	First part	Expansion part
	Safety, tolerability, and pharmacokinetics in patients with solid tumor will be evaluated and the maximum tolerated dose is determined.	Safety, tolerability, and exploratory efficacy will be evaluated in patients with advanced and/or recurrent hepatocellular carcinoma.

Drug Discovery and Development -Pipeline

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 trials in the USA and in Europe.

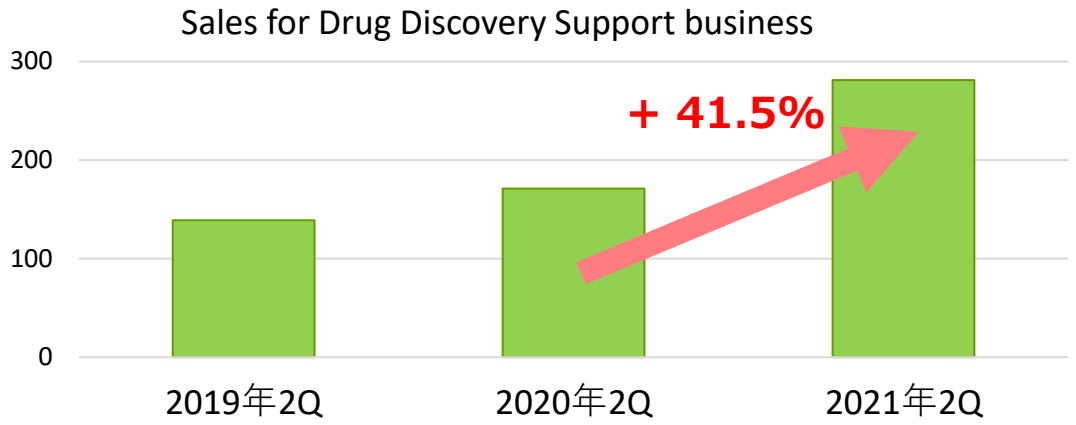
About National Cancer Institute(NCI)

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.

Drug Discovery Support

Sales increase in contract service

- Sales of JPY 438 mil., increased by 41.5% year-on-year, due to growth of business with key clients in Japan.



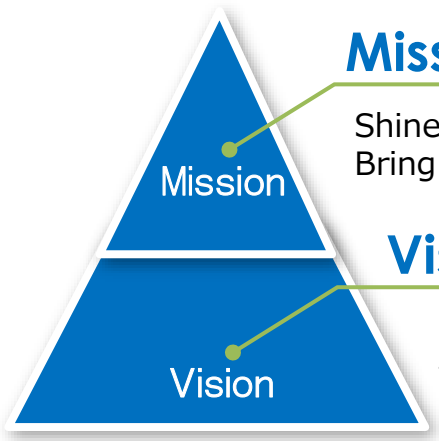
<Major clients>

	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

Corporate Overview

Biotech company dedicating to satisfy unmet medical needs



Mission

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

Vision

Will become No. 1 biotech venture that discovers and develops antibody drugs for 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 Mothers Section)

■ President and Chief Executive Officer:
Shigeru Kobayashi, M.E.

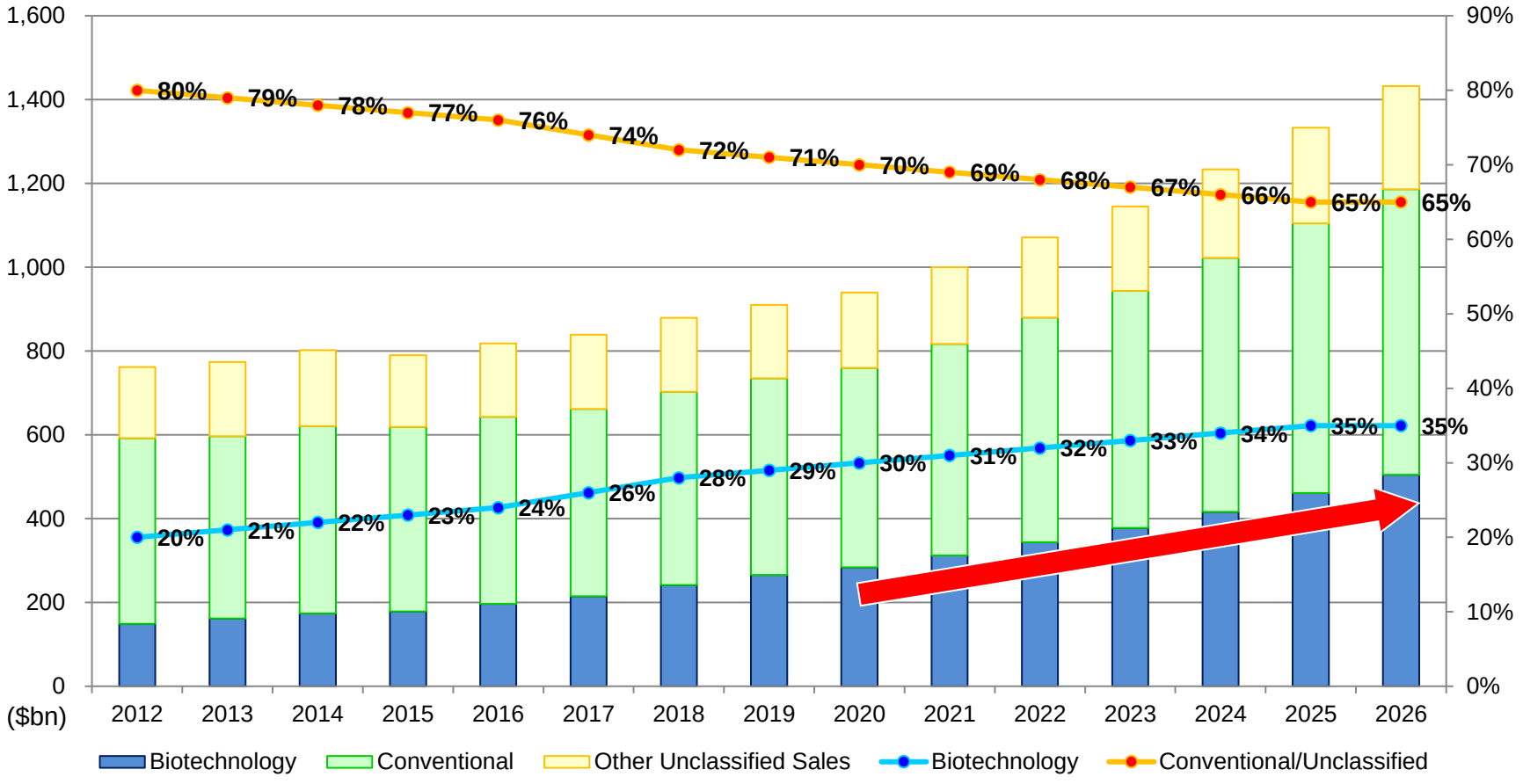
■ Location :
<Head Office and Research Laboratories>
3-12-1Honmachi, Shibuya-ku, Tokyo
<Drug Discovery Laboratories>
2-13-3 Nogawahonchou, Miyamae-ku, Kawasaki-city, Kanagawa

■ Number of Employees :
57 (As of June 30,2021)

■ 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.

Global Pharmaceutical Market Trends

Biotechnology, mainly antibody drugs driving growth in market



EvaluatePharma® World Preview 2020, Outlook to 2026

Leading antibody drugs

7 antibodies in the top 10 selling drugs worldwide

Sales ranking of prescribed drugs (2020)

NO	Product	Company	Main indication	Modality	Sales ($mil.)
1	Humira	Abbvie/Eisai	Rheumatoid arthritis	Antibody	20,389
2	Keytruda	Merck	Oncology	Antibody	14,380
3	Eylea	Regeneron/Bayer/Santen	Age-related macular degeneration	Recombinant protein	8,360
4	Stelara	J&J	Psoriasis	Antibody	7,975
5	Opdivo	Ono/BMS	Oncology	Antibody	7,888
6	Enbrel	Amgen/Pfizer/Takeda	Rheumatoid arthritis	Recombinant protein	6,346
7	Trulicity	Eli Lilly	Diabetes	Peptide	5,377
8	Avastin	Roche	Oncology	Antibody	5,321
9	Ocrevus	Roche	Multiple sclerosis	Antibody	4,612
10	Remicade	J&J/Merck/Mitsubishi Tanabe	Rheumatoid arthritis	Antibody	4,511

(Source) : Nikkei Biotech Online, partially edited

Differences between antibody and small molecule drugs

Antibody drug is a product of biotechnology

	Antibody	Small molecule
Side effects	Antibody, in general, are safe and causes less side effect, since it specifically targets cells and tissues relating to the disease, but not normal cells and tissues.	It is safe and harmless when they are used according to the approved condition.
Efficacy	Antibody directly attacks targets or signals that causes the disease, i.e., antibody aims for cure of the disease, not supportive care.	Drugs, particularly molecularly targeted drugs, are designed to directly attack targets or signals that causes the disease, i.e., it aims for cure of the disease, not supportive care. Small molecule drugs are often used as supportive care such like a painkiller.
Administration route	In general, injection and infusion at a hospital and clinic (Self-injection is available in some cases)	Injection, Oral, dermal, nasal, or topical, etc. Many of those can be taken at home under physician's instruction.
PK	Longer half-life in serum, which allows less frequent dosing such as weekly or monthly.	Relatively short half-life in serum. In some cases, daily dosing, 1-3 times a day, are required.
Target specificity	High (It's an essential concept of antibody)	Depends on the drug
Manufacturing process	Culture of microorganism or animal cells	Chemical synthesis, Culture of microorganism

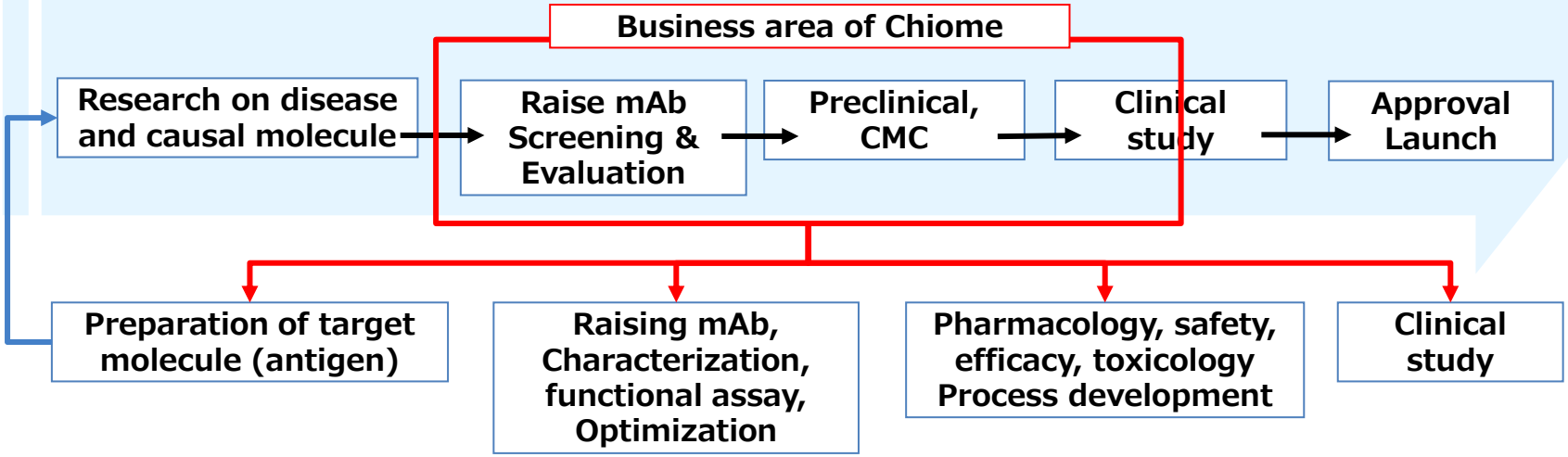
(Source) : Edited by Chiome based on the materials from Seed Planning

Chiome's business

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

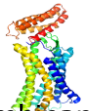
Protein Group	Antibody Discovery	Antibody Discovery Labs.	Clinical Development

Core competence for developing business

Technology Platform (Chiome's mAb Discovery Engine)

Preparation of recombinant proteins

Expression



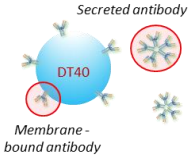
Recombinant proteins

Membrane proteins

Purification

MAb Generation Platform

ADLib®system



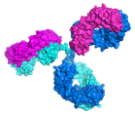
Animal immunization

B cell cloning

Hybridoma

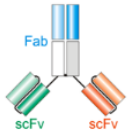
MAb Engineering

Affinity maturation



Functional evaluation

Multi-specific antibody



Lab-scale mAb production

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

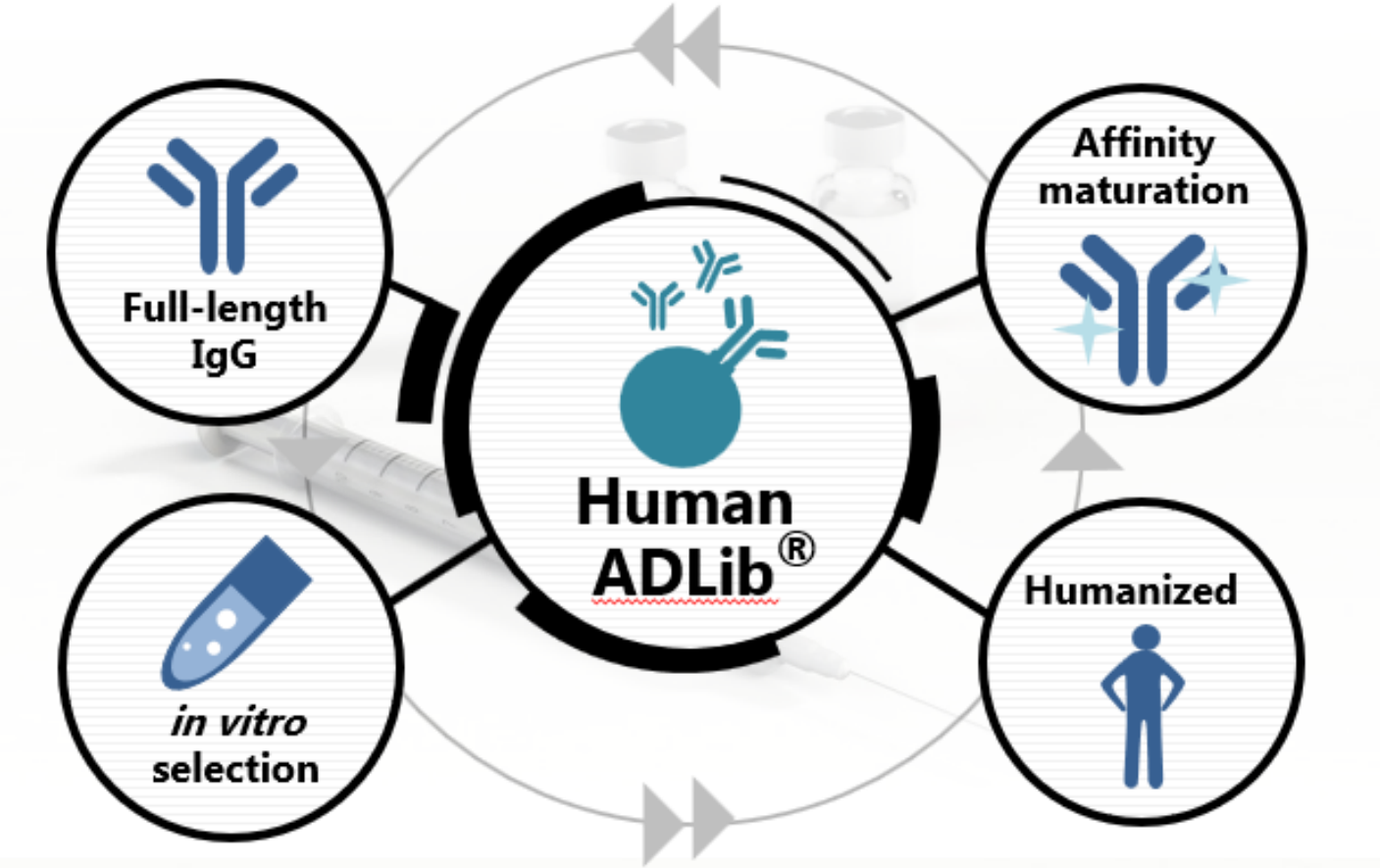
Development of therapeutic drug and diagnostic agent

Drug Discovery Support

Contract service for drug discovery

Core technology : Human ADLib®System

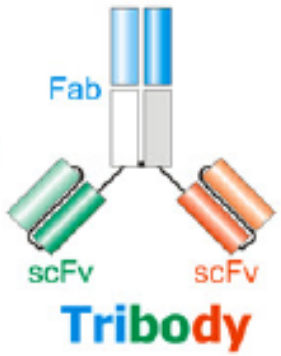
One-stop-order platform for antibody drug discovery



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 : Tribody™

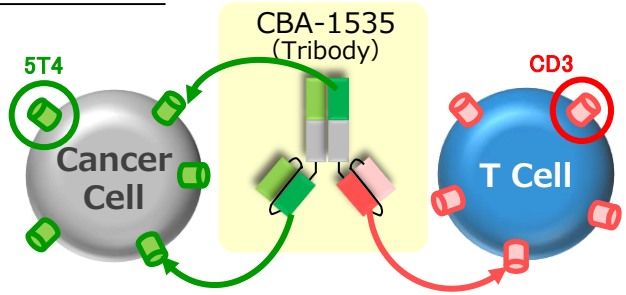
Tribody™



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

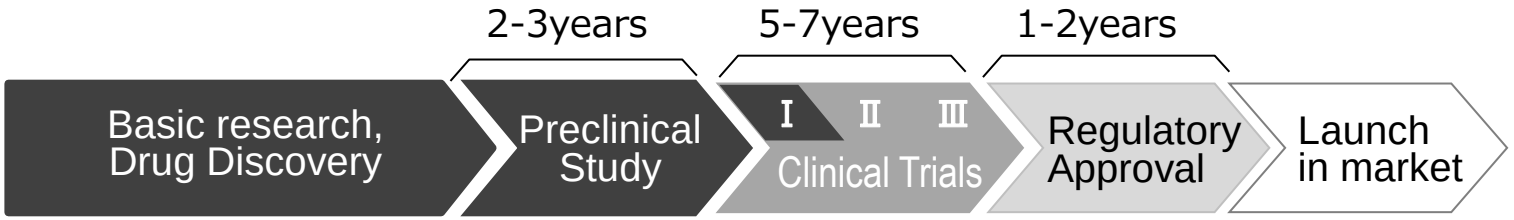


One of the binding sites can be designed to recruit immune cells (effector cells) with cytotoxic activity, such as T cells and NK cells, and the remaining 2 sites can be designed to bind to different epitopes of a cancer-specific antigen or to recognize different antigens expressed on the cancer cell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

Tribody™ enables creation of unique antibody by building multi-binding sites that bind to different antigen or epitope, which differentiate from conventional antibody.
Chiome strives for developing an antibody drug with greater safety and higher efficacy.

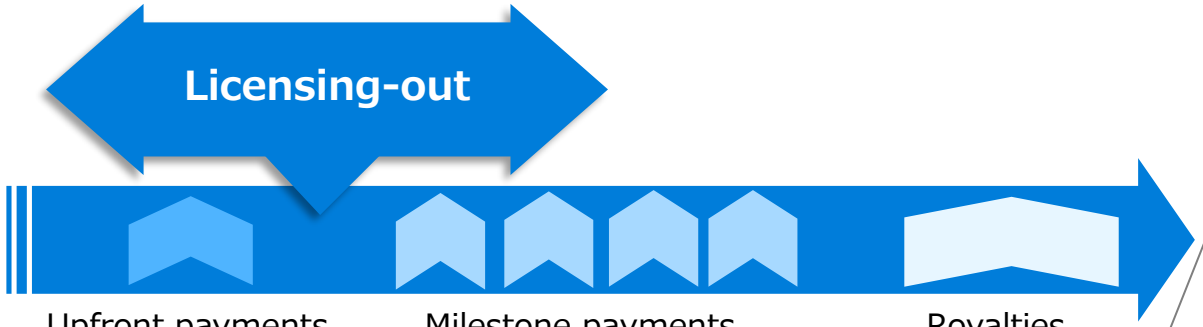
Revenue Model

Drug development process and Chiome's revenue model



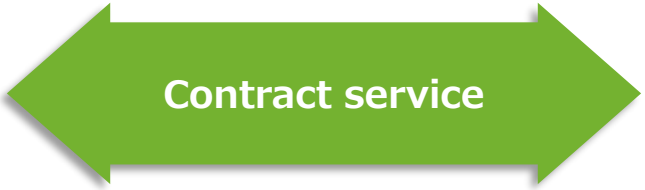
Drug Discovery

Revenues by licensing-out patents of pipeline product and drug candidates to pharmaceutical companies.



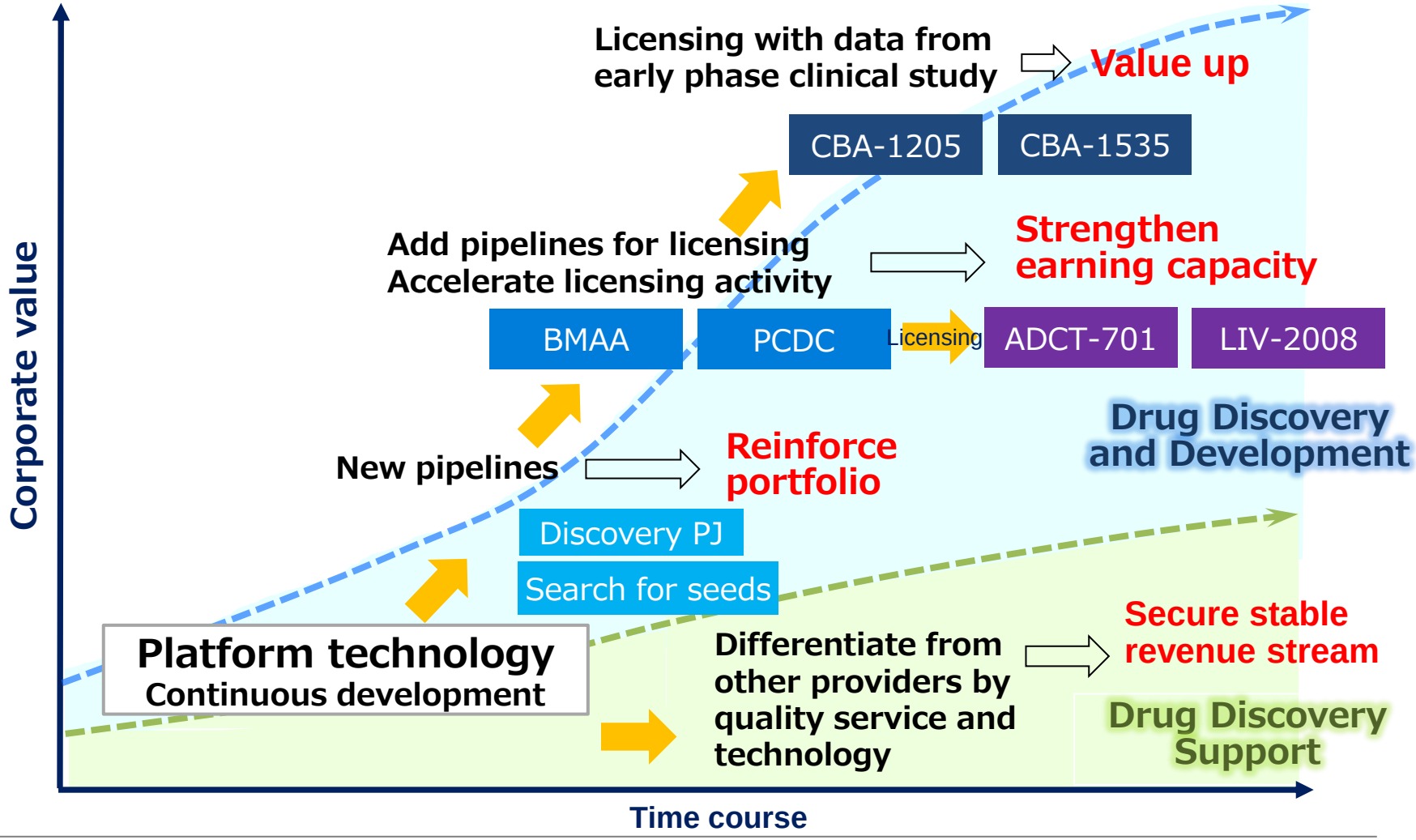
Drug Discovery Support

Revenues by providing services relating to antibody and protein to pharmaceutical and diagnostics company, and academia.



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.



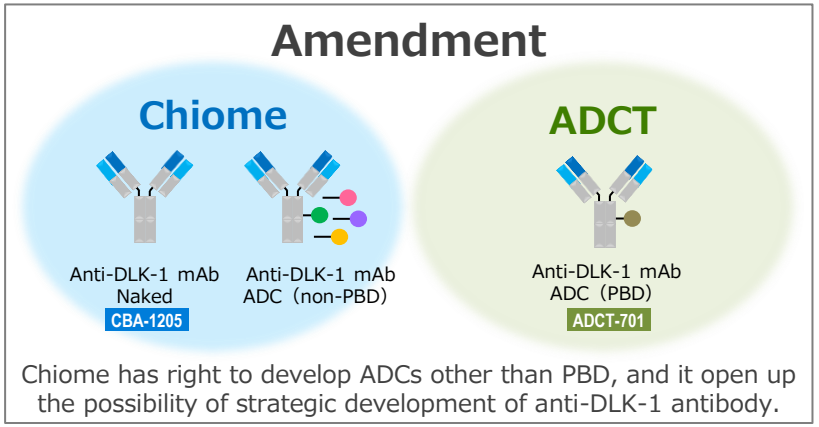
Appendix. Pipeline information

Pipeline -Out-Licensed-

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)

- ✓ Under the License Agreement, Chiome granted ADCT a worldwide exclusive license with a right to sublicense, develop, manufacture, and commercialize an ADC format of LIV-1205, which is coded “ADCT-701”.
- ✓ With the amendment executed in November 2020, Chiome obtains greater flexibility in advancing strategic drug development of anti-DLK-1 antibody, also increase the licensing opportunity and business potential of CBA-1205.
- ✓ ADCT has completed pharmacology and toxicology studies required for an IND submission and is continuing preparations for an IND.



Pipeline -Out-Licensed-

LIV-2008（Humanized anti-TROP2 antibody）

Henlius

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 also expected to play a key role in 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社HP： HKEX-EPS_20210114_9583899_0.PDF (windows.net)）

Pipeline -In-house program-

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 without effective therapeutic drugs including hepatocellular carcinoma.
Patent	Granted in Japan, US, Europe, China etc.

- ✓ The first patient has been dosed CBA-1205 in First-in-Human Phase 1 study in July 2020.
- ✓ Dose escalation part of Phase I Study to see safety is on-going well on track at National Cancer Center Hospital.
- ✓ Expect moving to Part 2 in HCC patients at the end of 2021 or the first half of 2022.
- ✓ Implementation of combination study with anticancer drugs for CBA-1205 and file patent applications.

Market analysis of Liver Cancer

No. of patient※1	840,000 new cases worldwide in 2018 The second leading cause of cancer-related deaths. High incidence in Africa and Asian region.
DLK-1 expression※2	Ca.20% of liver cancer patients and ca. 50% of lung cancer patients express DLK-1
Standard treament※3	Surgery is the first choice if it is resectable 1. Surgery : Resection of tumor 2. Ablation : percutaneous ethanol injection, Radiofrequency ablation 3. Embolization Drug therapy is applicable for post-surgery, unresectable advanced stage.
Competitor	Sorafenib, Lenvatinib, Atezolizumab - Bevacizumab
Market	Combination therapy of anti-PD-L1 antibody and anti-VEGF antibody was approved in September 2020.

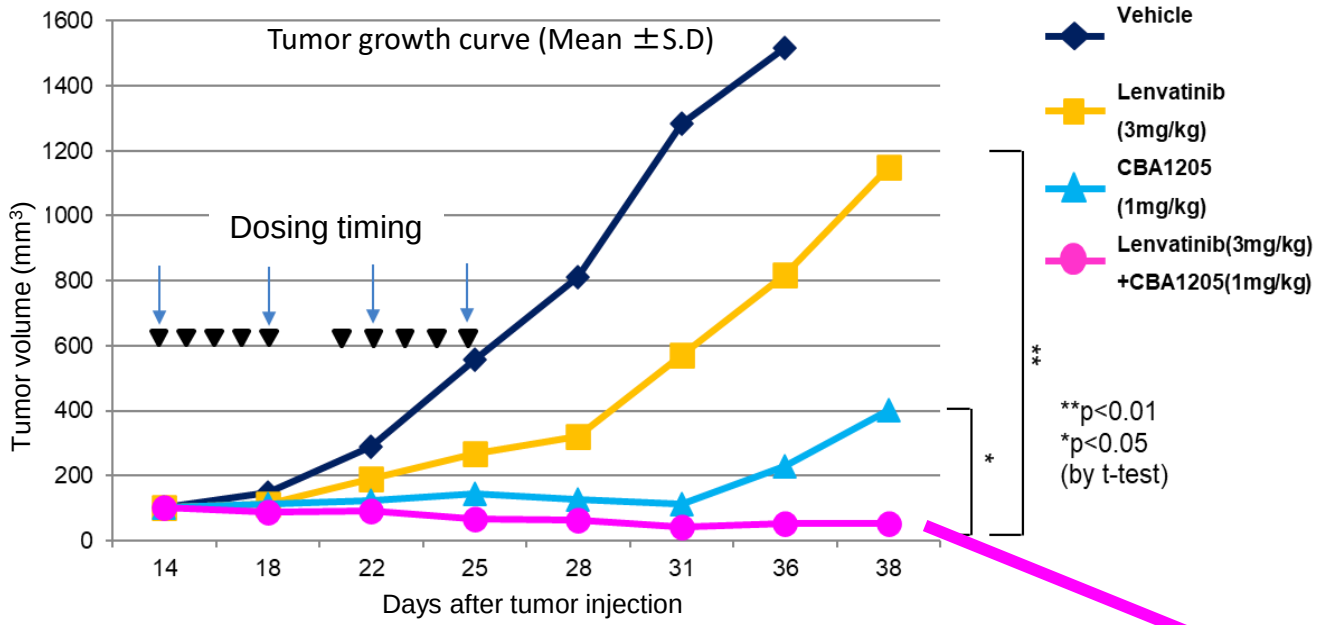
※1: http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/liver-cancer-statistics
※2: J. Biochem.: 148, 85-92 (2010)
※3: https://ganjoho.jp/public/cancer/liver/treatment.html

Pipeline -In-house program-

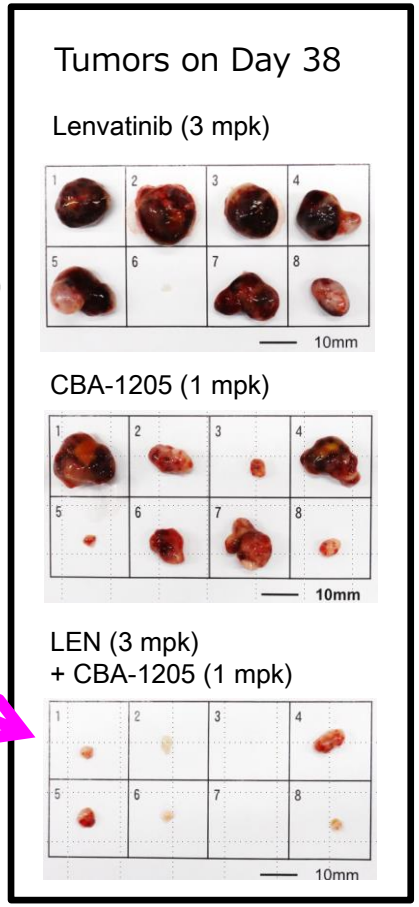
A patent application, "Combination of CBA-1205 and Lenvatinib" filed in 2019 is published

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



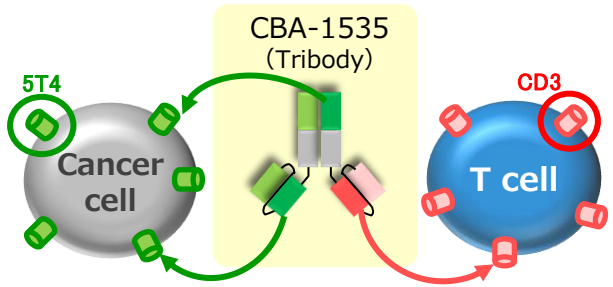
Remarkable tumor regression was observed in combination of CBA-1205 and Lenvatinib in HCC xenograft treatment model.

Pipeline -In-house program-

CBA-1535（Humanized anti 5T4 antibody, multi-specific 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 tri-specific format Offer a new treatment option for a disease which has poor prognosis and where there is only few effective treatment.
Patent	Granted in Japan, UK, US, China. Pending in Europe etc.

- ✓ CMC development has made progresses on schedule to date.
- ✓ The possibility of conducting Phase 1 study in Japan where COVID-19 gives less impact on development has been discussed. Upon a consultation with the PMDA, regulatory authority in Japan, we are convinced that we can submit an application with the existing data package in the first half of 2022.



Pipeline –Licensing-

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.

Pipeline –Licensing-

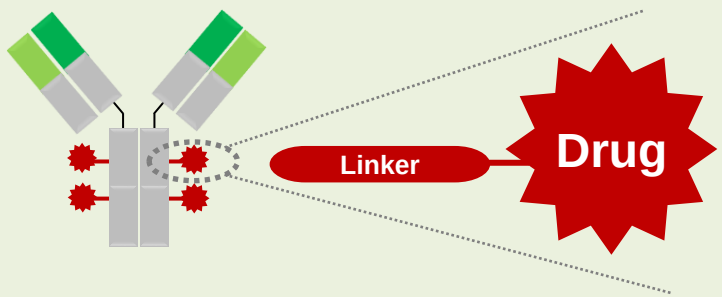
PCDC（humanized anti-CDCP1 antibody for antibody drug conjugate）

First in class

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

- ✓ Open for licensing opportunities as an antibody for ADC
- ✓ Additional *in vivo* efficacy/safety studies are ongoing.
- ✓ Patent application was published from WIPO (7/2021)

Antibody-Drug Conjugate Technology

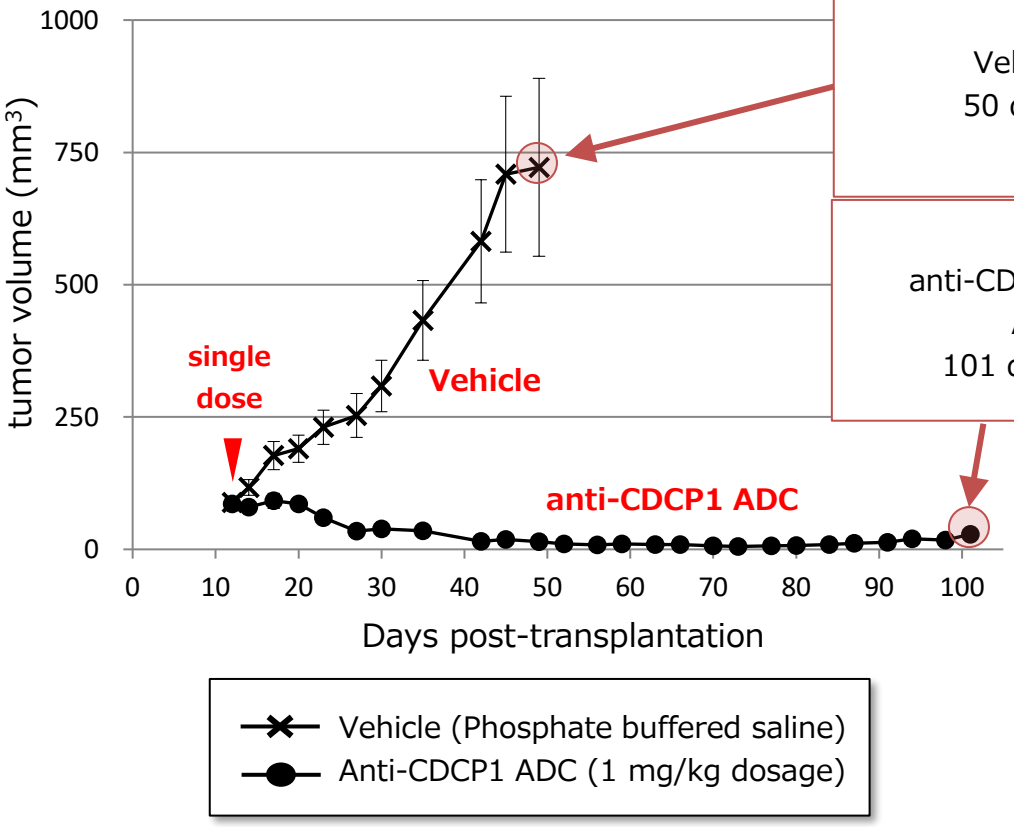


Pipeline –Licensing-

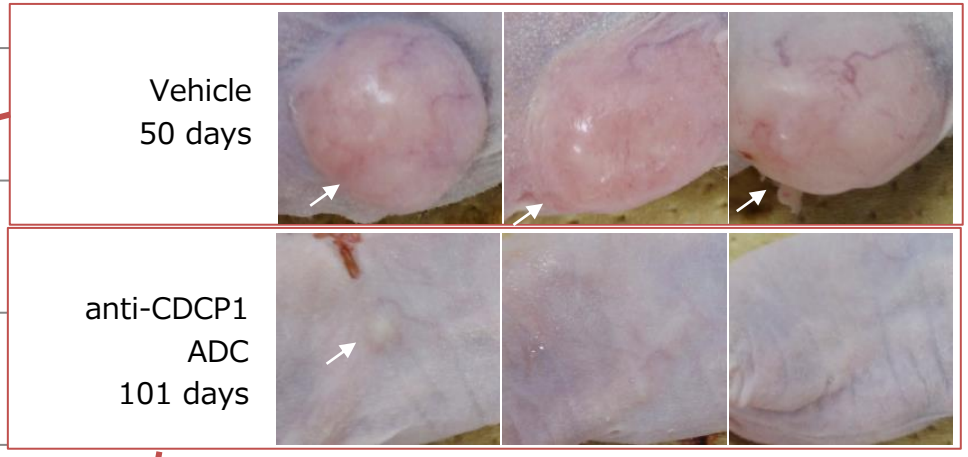
A patent application for PCDC "Anti-CDCP1 antibody" is published
~The antibody for highly effective antibody-drug conjugate against various solid tumors ~

Patent :WO/2021/132427

Anti-tumor efficacy against prostate cancer xenograft model



arrow : tumor



Tumors overexpressing CDCP1

- Lung
- Head & Neck
- Esophageal
- Colorectal
- Cervical
- Breast
- Ovarian
- Prostate
- etc.


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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