

# **Supplementary Information for Financial Results Q1 FY12/23**

May 11, 2023



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

Chiome Bioscience Inc.

#### **Agenda**



- 1. Overview of Q1 FY12/23 "Financial results"
- 2. Overview of Q1 FY12/23 "Operation highlights"

Appendix.

**Corporate information Pipeline information** 



# Overview of Q1 FY12/23 "Financial results"

# **Financial results: Profit and Loss**



(JPY in millions)

	Q1 FY2022	Q1 FY2023	Increase (decrease)	Main reasons for increase / decrease
Net sales	128	169	40	
Drug Discovery & Development	0	0	0	
Drug Discovery Support	128	169	40	
COS/SGA	615	395	(219)	
R&D Expense	446	193	(252)	CMC-related cost for CBA-1535 was recorded in Q1 FY2022
Other costs	169	201	32	Increase in sales cost due to business expansion in drug discovery support business and patent related cost
Operating Loss	(486)	(225)	260	
Ordinary Loss	(491)	(227)	263	
Net Loss	(492)	(227)	264	

# **Financial results: Balance Sheet**



(JPY in millions)

	As of Dec. 31, 2022	As of Mar. 31, 2023
Current assets	2,092	1,964
(Cash on hand in banks)	1,727	1,566
(Other current assets)	364	398
Non-current assets	123	120
Total assets	2,215	2,085
Current Liabilities	370	469
Non-current liabilities	54	54
Total liabilities	424	523
Total net assets	1,790	1,562
Total liabilities and net assets	2,215	2,085



# Overview of Q1 FY12/23 "Operation highlights"

#### **Key Topics**



1 PR(Partial Response) has been confirmed in hepatocellular carcinoma in the second part of CBA-1205 Phase I study. Will see the duration of response.

\*Final analysis results yet to be completed.

SD (stable disease) assessment with tumor shrinkage in a Malignant Melanoma patient from the first part of CBA-1205 Phase I study, has been lasting for more than 18 months.

\*Final analysis results yet to be completed.

Manufacturing of 2<sup>nd</sup> batch of the study drugs is taking place, and modification of the development plan in CBA-1205

Phase 1 study of ADCT-701 has been scheduled to initiate in 2023 by NCI.

In drug discovery support business, a master services agreement was concluded with a pharmaceutical company in Japan

#### **Operation highlights**



#### **Drug Discovery and Development - Pipeline**

CBA-1205	<ul> <li>✓ 1 PR(Partial Response: tumor shrinkage of 30% or more) has been confirmed in hepatocellular carcinoma in the second part of the study. Will see the duration of PR.</li> <li>✓ SD (stable disease) assessment with tumor shrinkage in a Malignant Melanoma patient from the first part of CBA-1205 Phase I study, has been lasting for more than 18 months. Dosing is still ongoing.</li> <li>✓ Based on the high tolerability of the study drug in the first part and multiple cases of long-term dosing, we have started manufacturing of 2<sup>nd</sup> batch of the study drugs to ensure that the second part of the study would be carried out. In addition, we will analyze the scientific relationship between PR cases and the dosing of the study drug to verify its therapeutic potential. We have decided to modify the selection criteria for patients enrolled in this second part of the study and to extend the study period (no change in the out-licensing schedule)</li> </ul>
CBA-1535	> Dose escalation to assess the safety and efficacy is conducted
PCDC	Promoting out-licensing activities mainly in the field of ADC applications.

#### **Pipeline - Out-Licensed programs**

**ADCT-701** 

✓ ADCT halts its investment in this project to focus on nearer-term value drivers. In ADCT corporate presentation in March Phase I clinical study was mentioned to initiate in 2023 by NCI.

#### **Drug Discovery Support Business**

Deals with pharmaceutical companies

- Forecast for FY12/2023 (net sales): ¥640 million
- A master services agreement was concluded with a pharmaceutical company in Japan

# **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

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
<b>★</b> 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.			leted new patent applications incology project and CNS	_

#### CBA-1205 Phase 1 study



# Confirmation of 1 PR in HCC patient (preliminary report) Change the development plan to increase out-licensing opportunity value



# Study design

#### First part (Dose escalation)

Safety, tolerability, and pharmacokinetics in patients with solid tumors will be evaluated and the maximum tolerated dose is determined.

- · No serious adverse event reported
- · SD (stable disease) assessment with tumor shrinkage in a Malignant Melanoma patient from the first part of CBA-1205 Phase I study, has been lasting for more than 18 months. Dosing is still ongoing.

#### Second Part (Expansion part)

Safety, tolerability, and exploratory efficacy will be evaluated in patients with advanced and/or recurrent hepatocellular carcinoma.

- 1 PR(Partial Response: tumor shrinkage of 30% or more) has been confirmed in hepatocellular carcinoma in the second part of the study. Will see the duration of PR.
- Manufacturing additional study drugs to deal with longer-term dosing cases.
- Analyzing the scientific relationship between PR cases and the dosing of the study drug to verify its therapeutic potential.
- Modifying the criteria for patients screening in this second part and extending the study period (no change in the out-licensing schedule)

# **CBA-1205** First part of Phase 1 study (Safety)



#### No toxicity of Grade 3 or higher were observed High level of safety was confirmed

			D	ose (mg/k	g)			Total
Adverse Events	0.1	0.3	1	3	10	20	30	Total
Adverse Events	(n=3)	(n=3)	(n=3)	(n=4)	(n=3)	(n=3)	(n=3)	(n=22)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Adverse Events								
Total Patients with AEs	3 (100)	2 (66.7)	3 (100)	4 (100)	3 (100)	3 (100)	3 (100)	21 (95.5)
Grade 1-2	3 (100)	2 (66.7)	3 (100)	4 (100)	3 (100)	3 (100)	3 (100)	21 (95.5)
≥ Grade 3	2 (66.7)	1 (33.3)	0	0	1 (33.3)	1 (33.3)	1 (33.3)	6 (27.3)
SAEs	1 (33.3)	1 (33.3)	0	0	1 (33.3)	1 (33.3)	1 (33.3)	5 (22.7)
Death	0	0	0	0	0	0	0	0
Treatment Discontinuation	0	0	0	0	1 (33.3)	0	0	1 (4.5)
CBA-1205 Related AEs								
Patients with CBA-1205 Related AEs	1 (33.3)	0	2 (66.7)	3 (75.0)	1 (33.3)	2 (66.7)	3 (100)	12 (54.5)
Grade 1-2	1 (33.3)	0	2 (66.7)	3 (75.0)	1 (33.3)	2 (66.7)	3 (100)	12 (54.5)
≥ Grade 3	0	0	0	0	0	0	0	0
DLT	0	0	0	0	0	0	0	0
SAEs	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Treatment Discontinuation	0	0	0	0	0	0	0	0
Common TRAEs (PT) ≥ 20%								
Pyrexia	0	0	0	1 (25.0)	0	2 (66.7)	3 (100)	6 (27.3)

Data as of February 3, 2023.

Grade is based on Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

# **CBA-1205 Out-licensing plan**



	2022 2023 2024 202					
P1 First Part	P1 Second Part					

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



Promote out-licensing activities in as well as conducting Phase 1 second part

Aiming to maximize upfront payment licensing deal by obtaining multiple PR cases in

HCC patients

## CBA-1535 Phase 1 study



# The first part of CBA-1535 Phase I study is in progress

202	21	2022		2023	2024
CMC develop Preclinical		★ Submission of CTA  ★ Dosing star		l end June study (First part)	
				Phase 1	study (Second part)
			В	usiness alliances and	l licensing activities
			Ref	-	-1535 started alongside ctivities of PCDC
Study design	<ul> <li>First part (single agent)</li> <li>Target: Solid cancer patients</li> <li>Starting to administer a low dose in increments to find the maximum dose that can be safely administered.</li> <li>Evaluate initial drug efficacy signals</li> </ul>		е	<ul> <li>immunotherapy drug</li> <li>Target: Solid cancer p</li> <li>Administer the dose safe in the first part in the first part in the maximum d</li> </ul>	patients that was confirmed to be in increments. ose that can be safely ombined with cancer is (IOs)

#### 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.

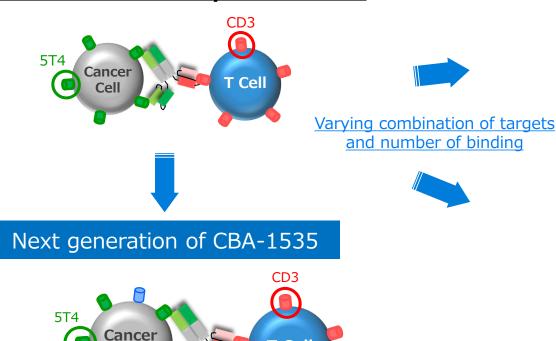
# Potential applications for Tribody™



By varying combination of targets and number of binding

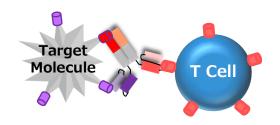
- 1) More effective than normal antibodies are expected
- 2) Co-administration of multiple drugs⇒single drug administration (merits such as patients' QOL, healthcare economic benefits are expected)

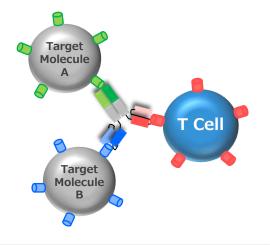
#### CBA-1535 (currently in Phase I)



T Cell

#### Target other than 5T4





Cell

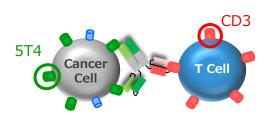
## **PTRY New Pipeline**



# 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

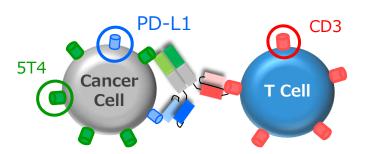
CBA-1535  $(5T4 \times 5T4 \times CD3)$ 



The binding site for PD-L1 is introduced



PTRY  $(5T4 \times CD3 \times PD-L1)$ 



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

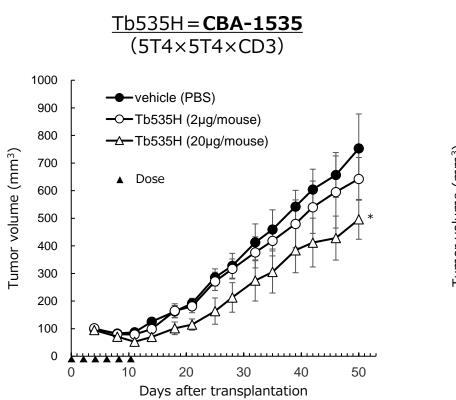
Novel tri-specific tribodies induce strong T cell activation and anti-tumor effects in vitro and in vivo | Journal of Experimental & Clinical Cancer Research | Full Text (biomedcentral.com)

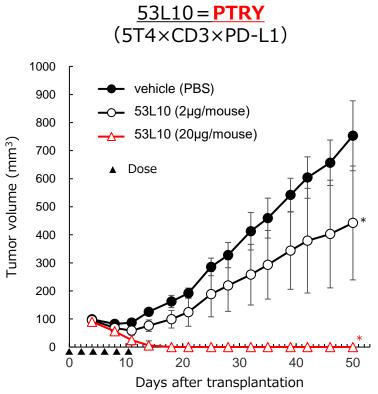
#### PTRY Efficacy of the drug in vivo



#### 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





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

# **PCDC** Out-licensing plan



First in class

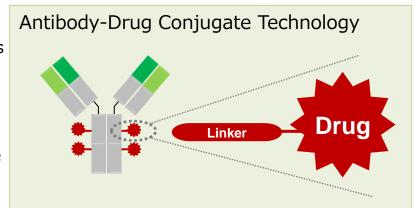
#### PCDC (humanized anti-CDCP1 antibody for antibody drug conjugate)

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
- 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

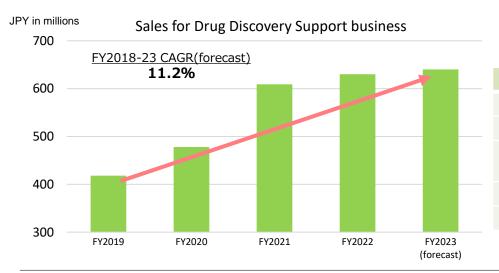


#### **Drug Discovery Support business**



#### Sales increase in contracted services

- Net sales for 1Q FY12/2023: ¥169 million
- The amount of business with existing clients is steadily increasing, as domestic pharmaceutical companies highly evaluate our technical service capabilities.
- A master services agreement was concluded with a major pharmaceutical company in Japan. In addition, continuously initiate business with new clients (spot deals).
- Forecast net sales of ¥640 million in the drug discovery support business in FY12/2023



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

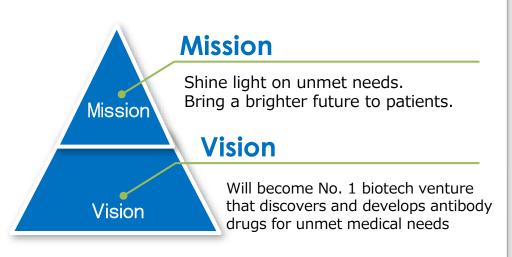


# **Appendix.** Corporate information

#### **Corporate Overview**



#### Biotech company dedicating to satisfy unmet medical needs



#### 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: 66 (As of Mar. 31, 2023)
- 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.

#### **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**

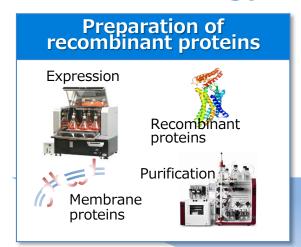
This is business to obtain revenues from antibody generation service by using platform technology that Chiome possesses to support drug discovery research at pharmaceutical companies, or for diagnostic and research purposes at academia or institutes on fee-for-service scheme.

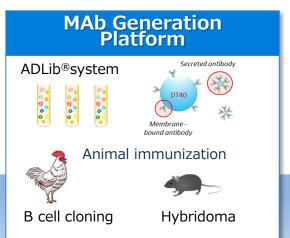
It secures constant revenue stream.

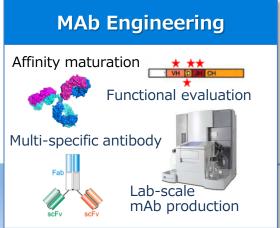
#### **Core competence for developing business**



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







#### **Advantage**

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.

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

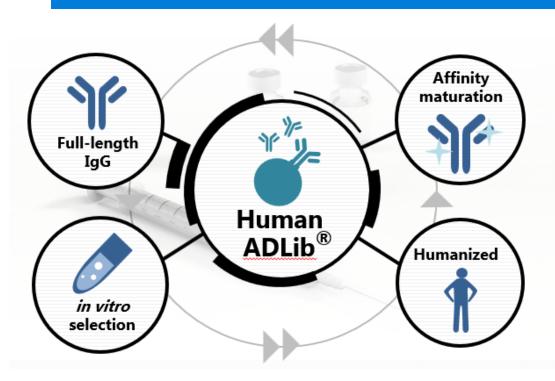
#### **Drug Discovery Support**

Contract service for drug discovery

# **Core technology: 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.

The usefulness of the technology in antibody drug discovery and development of the human ADLib system was published in [Cellular & Molecular Immunology].

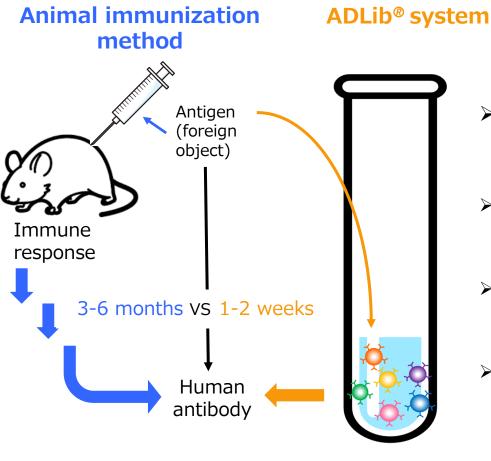
(Collaborative research results with the Department of Life Sciences, Graduate School of Arts and Sciences, The University of Tokyo)

Title: Streamlined human antibody generation and optimization by exploiting designed immunoglobulin loci in a B cell line (https://www.nature.com/articles/s41423-020-0440-9)

# Core technology that support 2 businesses: ADLib® 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

ADLib® Library

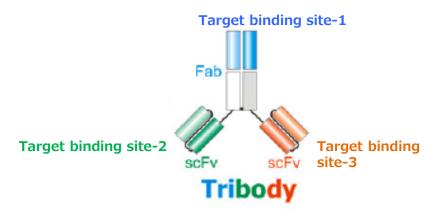
# Core Technology: Tribody<sup>TM</sup>(Multispecific Antibody Production Technology)



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

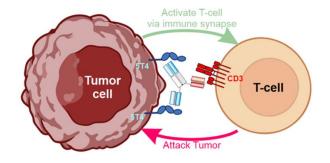
#### What is Tribody™

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<sup>TM</sup>

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



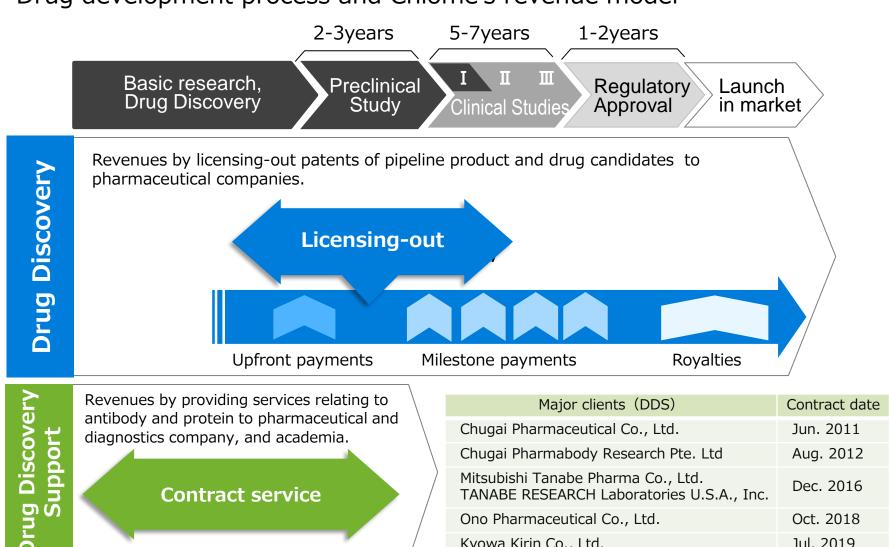
Two hands firmly hold the target and pull the cancer-attacking cells close to the cancer cell with a third hand

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

#### Revenue Model



#### Drug development process and Chiome's revenue model



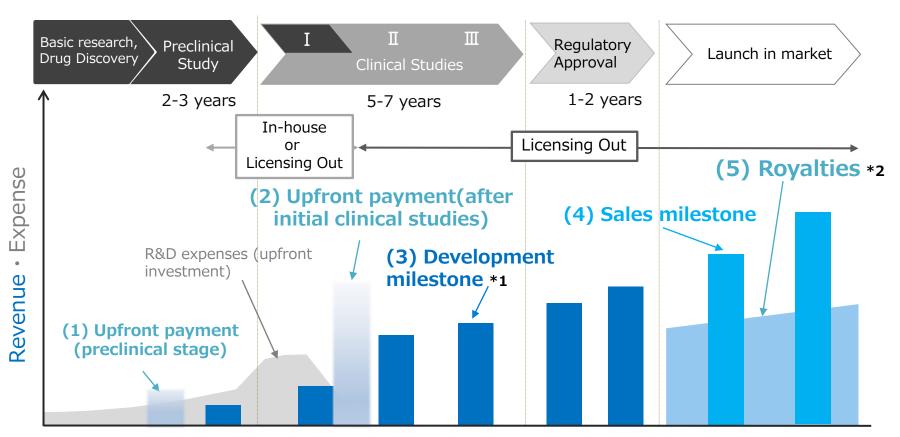
Kyowa Kirin Co., Ltd.

Jul. 2019

## 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.

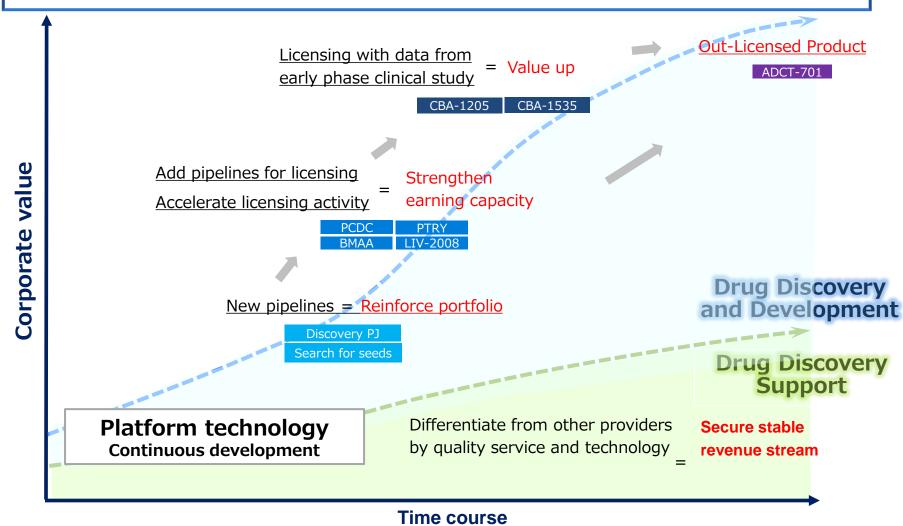
<sup>\*1</sup> Milestone: Income received by the licensee at each milestone after out-licensing through the progress of clinical studies and others.

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

### **Business strategy for the future growth**



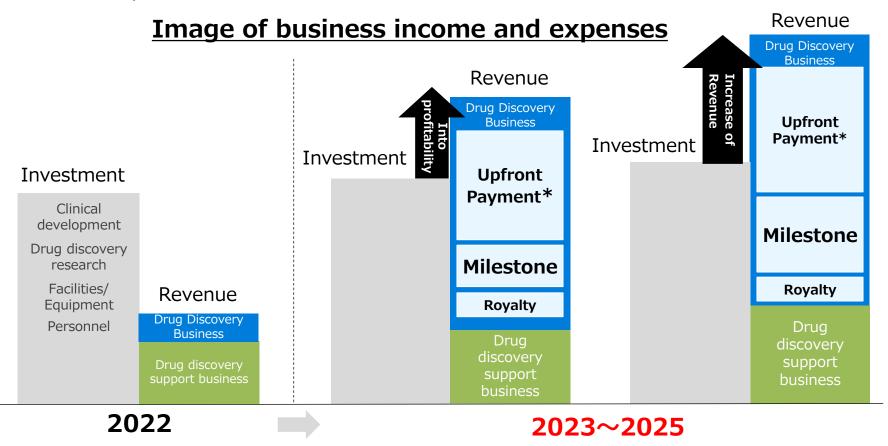
Create candidate of innovative antibody drugs for unmet medical needs and pay maximum efforts to increase the corporate value by developing and licensing highly valuable antibodies.



#### Image of transitioning to profitability



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



<sup>\*</sup>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**

### 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 )

- ADCT-701 is an antibody-drug conjugate of the antibody LIV-1205 developed by Chiome and PBD\* (\*Pyrrolobenzodiazepine : Drug with anti-tumor properties)
- ✓ ADCT halts its investment in this project to focus on nearer-term value drivers.
- ✓ (In ADCT corporate presentation in March) Phase I clinical study was mentioned to initiate in 2023 by NCI.

#### 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.

### 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 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

- > No serious adverse reaction reported.
- > SD (stable disease) evaluation with tumor shrinkage has been continued in a patient with Melanoma and the continuous dosing period has exceeded more than 18 months. Dosing is still ongoing.

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

> One PR(Partial Response) case has been confirmed and longer duration of response is expected.

# Pipeline -In-house program-



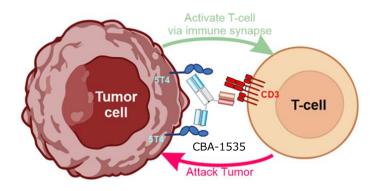
#### CBA-1535 (Humanized anti 5T4 & CD3 trispecific antibody)

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



## **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.

- We are promoting joint research with Academia based on the data which we have obtained to date.
- The data obtained so far on Semaphorin 3A and the exploratory research data (Semaphorin family) will be used for future business development activities.

#### **Pipeline -Licensing-**



#### 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.

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



#### Disclaimer



- Materials and information provided during this presentation may contain so-called "forward-looking statements." These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements.
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