

Fiscal year ended August 2024

# **Financial Results Presentation**

Chordia Therapeutics Inc.

(TSE securities code: 190A)

October 15, 2024

# Agenda

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# Company overview (as of August 2024)

**Company overview** 

Name	Chordia Therapeutics Inc.
Securities code	190A
Established	October 12, 2017
Representative	Hiroshi Miyake, Ph.D. CEO
Head office	2-26-1, Muraoka Higashi, Fujisawa City, Kanagawa Prefecture, Japan
No. of employees	22 (including 12 Ph.D. holders)
Share Capital	844,100,500 yen
Total Financing	About 9.7 billion yen

**History** 

	Oct	Established Chordia Therapeutics Inc. in Shonan iPark, Fujisawa City, Kanagawa Prefecture, Japan
2017	Nov	Entered into a license agreement with Takeda Pharmaceutical Company Limited (Takeda) for exclusive worldwide rights to 4 programs
	INOV	<ul> <li>Entered into an investment agreement with Takeda, Kyoto Innovation Capital Corporation (Kyoto iCAP) and other underwriters</li> </ul>
2018	Aug	Initiated Phase 1 Clinical Trial for CTX-712 in Japan
2019	Mar	Entered into stock purchase agreement with JAFCO Group, KYOTO-iCAP and several other companies as underwriters
	Apr	Established the Tokyo Office in Chuo-ku, Tokyo
2020	Dec	Entered into a license agreement with Ono Pharmaceutical to grant exclusive rights to develop, manufacture, and commercialize our anti-cancer compound CTX-177 and its related compounds
		<ul> <li>Entered into stock purchase agreement with Japan Growth Capital, UTokyo Innovation Platform and several other companies as underwriters</li> </ul>
	May	Entered into a basic agreement on business tie up with MEDIPAL HOLDINGS CORPORATION
2022		Entered into a basic agreement on collaboration with Shionogi Pharma Co., Ltd
	Aug	Commenced Phase 1 clinical trial for CTX-177 in the U.S. through Ono Pharmaceutical, the licensee
	Sep	Received the "Ministry of Education, Culture, Sports, Science and Technology (MEXT) Award"
2023	Feb	Commenced Phase 1/2 Clinical Trial for CTX-712 in the U.S.
2023	Jun	Completed enrolled cases for Phase 1 clinical trial of CTX-712 in Japan
2024	Jun	Listed on the Growth market of the Tokyo Stock Exchange

#### **Governance structure**

Chordia has established a robust corporate governance structure with the former head of research at Takeda's Oncology Drug
Discovery Unit as the sole executive director. This structure is monitored by an experienced and diverse group of outside
directors.

#### **Executive Director / Representative Director**

#### **CEO: Hiroshi Miyake**



- He is a co-founder of Chordia Therapeutics and he has served as CEO since Chordia's incorporation in November 2017
- Prior to joining Chordia, he worked in the research area at Takeda Pharmaceutical Company, and after a secondment to Takeda San Diego, he has been the Japan Site Head of the Oncology Drug Discovery Unit since 2014
- He has over 20 years experiences in drug discovery and his team delivered a program to clinical stage six times
- He earned his B.S. from Osaka University and Ph.D. in Pharmacology from the University of Tokyo

#### **External Director**



Akihiko Shimauchi
(Former founder of INDEE MEDICAL and president of M's Science)

Business

**Expertise** 

#### **External Directors / Members of Audit & Supervisory Committee**



Kosuke Ishii (CPA and External Director of RaQualia Pharma Inc.)

**Accounting** 



Yukari Nishikata (Former Head of Takeda's Oncology Unit in Japan and Asia)

R&D



Ayuko Hashimoto (Legal Attorney: *Kotto Dori Law Office*)

Legal

#### Chordia's features

•Our hybrid model enables us to search seeds through collaboration with academia and conduct R&D to bring drugs to market through our drug discovery capabilities cultivated at pharmaceutical companies

# Spin out from Takeda with seasoned drug discovery researchers



# Outstanding experience and network based on collaboration with academia

Academic Startups 2022\*
"Ministry of Education, Culture, Sports,
Science and Technology (MEXT) Award"

6th Japan Open Innovation Award "Minister of State for Science and Technology Policy Award"

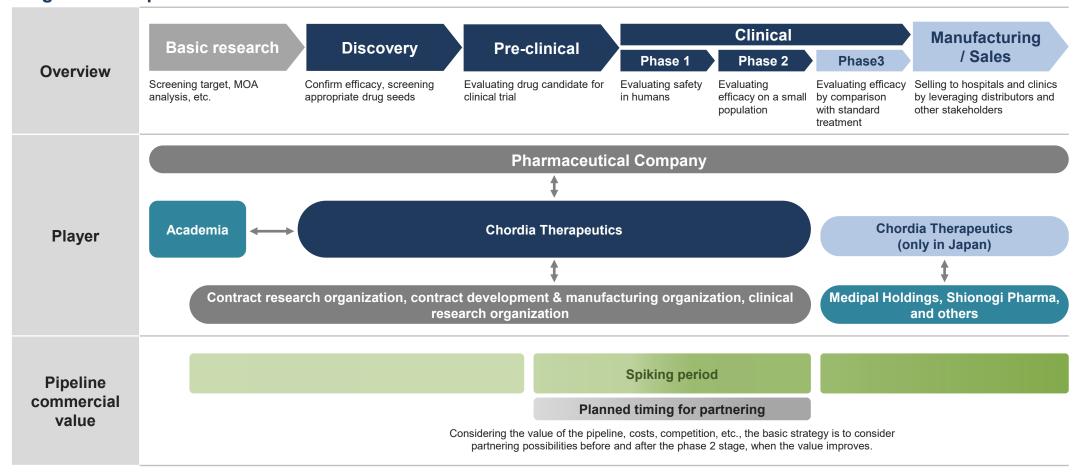
6th Japan Medical Research and Development Award "Startup Encouragement Award"

Nippon Startup Award 2024
"Minister of Education, Culture, Sports,
Science and Technology (MEXT) Award"



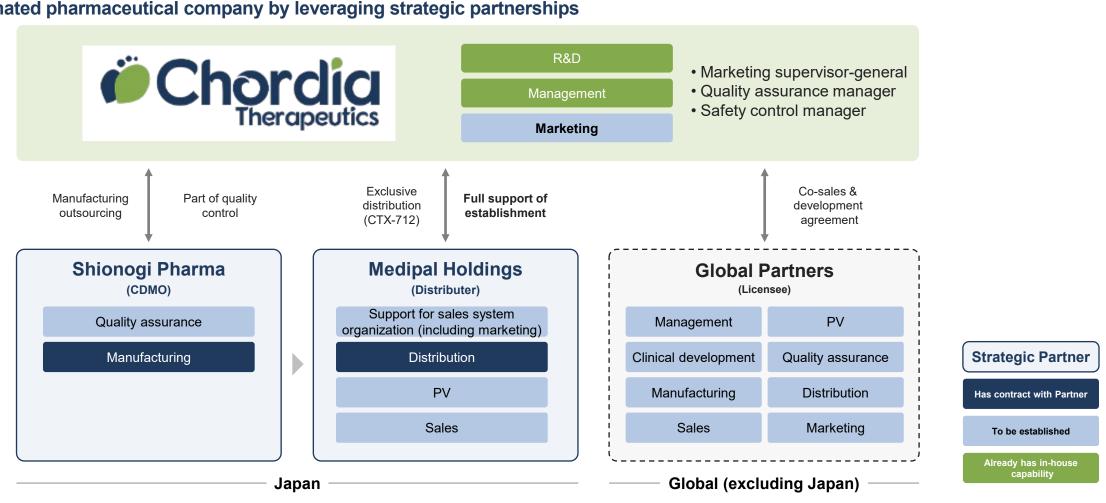
# Chordia's business model is based on a high-value pipeline with an established clinical POC

Our core business covers drug discovery to clinical research, with the potential to lead manufacturing and sales in Japan while licensing outside Japan



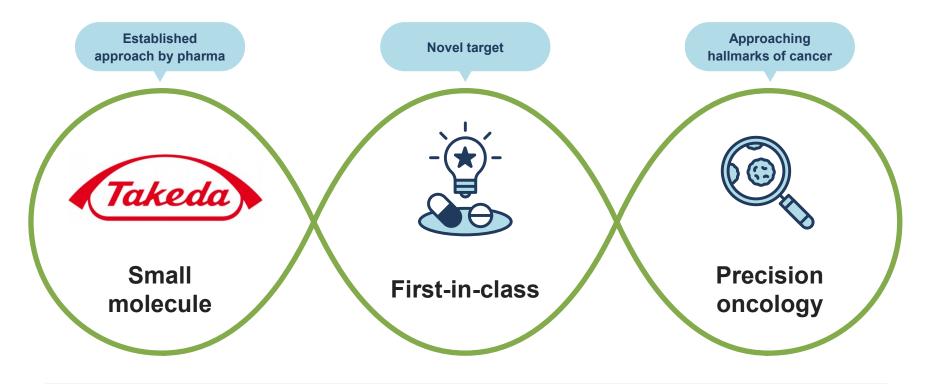
# Strategic partnerships aiming to become a Japan-originated pharmaceutical company

• Chordia's business strategy is to establish a manufacturing and sales structure that will enable the Company to become a Japanoriginated pharmaceutical company by leveraging strategic partnerships



## Chordia's positioning as a global standard

• Developing first-in-class small-molecule anti-cancer drugs by leveraging R&D capabilities with the assets, know-how, and network of Takeda



Challenging high-risk targets with low-risk drug discovery approach
Proceeding to increase success rate by considering hallmarks of cancer

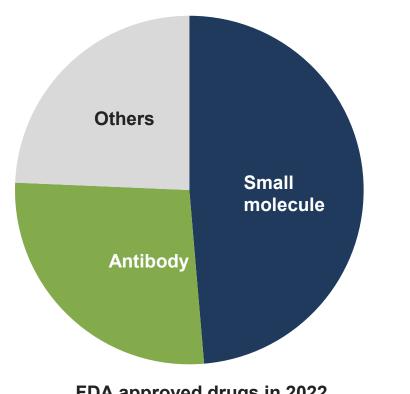
# Chordia's positioning ~ Small molecule compound drug discovery

• The discovery of small molecule drugs represents a significant proportion of approved drugs and is regarded as a well-established and mainstream approach to drug discovery

#### Market forecast for key modality

Growth amount (2022-2028)		Compound annual growth rate (CAGR) (2022-2028)
\$137 billion	Small Molecule	4.3%
\$132 billion	Antibody	8.4%
\$6 billion	Cell therapy	48.8%
\$16 billion	Gene therapy	45.3%

#### **Newly approved drugs by modality**



FDA approved drugs in 2022

# Chordia's positioning ~ First-in-class drug discovery

• First-in-class drug discovery, which has the potential to produce innovative new drugs and is risky, tends to attract interest from large pharmaceutical companies because of its innovativeness and potential marketability

#### What is first-in-class drug discovery?

Innovative pharmaceuticals

with high novelty and usefulness that could significantly change the conventional treatment system

Safety and efficacy are difficult to predict because of the novel mechanism of action

May be very effective in patients who have not responded to previous therapies

Once approved, has the potential to dominate the market primary because it will be on the market for the first time

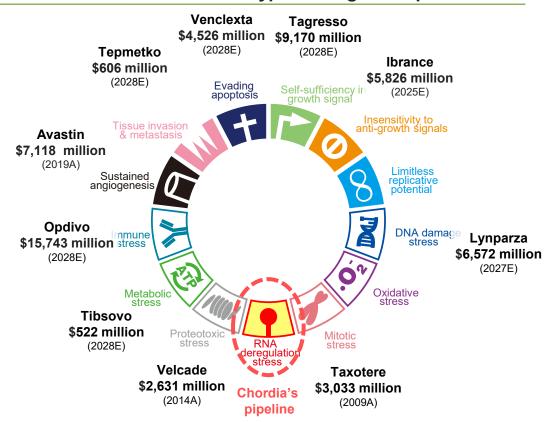
High drug prices could be expected because of high novelty and high difficulty

With interest from large pharmaceutical companies, and large-scale licensing agreements can be expected

# Chordia's focus on hallmark of cancer ~ RNA deregulation stress

- There are many effective anti-cancer drugs with substantial market size that target cancer hallmarks
- RNA deregulation stress is newly discovered as one of the cancer hallmarks and emerging fields in new anti-cancer drug discovery

#### Thirteen cancer hallmarks & typical drugs with peak sales(1)



Sources: Prepared by Chordia Therapeutics based on disclosure materials provided by Weinberg 2000, Elledge 2009, Meyerson 2012, Evaluate Pharma, Eisai

(1) Estimate of the maximum global market size potentially addressable by successfully developing anti-cancer drugs targeting any of the so-called Cancer Hallmarks and does not represent the potential market size for the Company's current or future pipeline. Figures for each anti-cancer drug indicate the sales amount in the year of the largest sales.

# Landscape overview of therapies targeting the stress phenotypes of cancer

- There are anti-cancer drugs that have been developed and marketed that target the DNA damage-induced stress and proteotoxic stress, which are the hallmarks of cancer cells
- On the other hand, drugs targeting RNA deregulation stress have never been marketed to date and remain a white space. Chordia is in the process of developing anti-cancer drugs targeting such research areas

Current landscape of marketed drugs targeting the DNA, RNA and protein-related stress phenotype of cancer and status of Chordia's pipeline under development

	DNA damage stress		RNA deregulation stress			Proteotoxic stress		
	DNA replication	RNA transcription	RNA splicing	RNA degradation	RNA transfer	Traffic	Degradation	
Marketed drugs (target)	PARP1/2 (Olaparib)	-	-	-	-	XPO1 (XPOVIO)	Proteasome (VELCADE)	
Chordia's pipeline	-	CDK12 (CTX-439)	CLK (CTX-712)	Chardia Therapeutics	Chardia Therapeutics GCN2	-	-	

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# Concept of stressing out cancer to the point of no return

- Normal cells can tolerate additional stress since they are exposed to less stress than cancer cells (left image)
- As cancer cells are exposed to numerous cellular stresses, applying additional stress potentially kills cancer cells due to stress overload (right image) (1)

# Normal cell Cancer cell Applying additional stress Cancer cell Applying additional stress

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<sup>\*</sup>For illustrative purposes only. Prepared by the Company (1) Source: Cell. 2009 Mar 6:136(5):823-37

# **Chordia's current ESG strategy**

Governance

• In addition to contributing to society through the creation of new drugs, which is the core of our business, we are actively working on environment considerations, female advancement, next-generation education, and information disclosure

Sustainable Chordia's focus Contents 17 goals Paper materials are not distributed at company meetings, and a paperless system is implemented **Environment conscious** Environment management · We have an environment that allows remote work, and about half of our employees actively use remote work 3 すべての人に 健康と福祉を • Phase 1 clinical trial for cancer patients who no longer **Creating innovative drugs** receive standard treatment, confirming efficacy in multiple patients 5 ジェンダー平等を 実現しよう About 40% of Board of Directors are female ₫ Social **Diversity & inclusion** Contributed to several educational programs, including **Cultivating the next generation** lecturing at Koryo High School and giving lectures at Ritsumeikan University

· Independent external directors who take the lead in

disclosure account for 80%

Appropriate disclosure to

shareholders and stakeholders

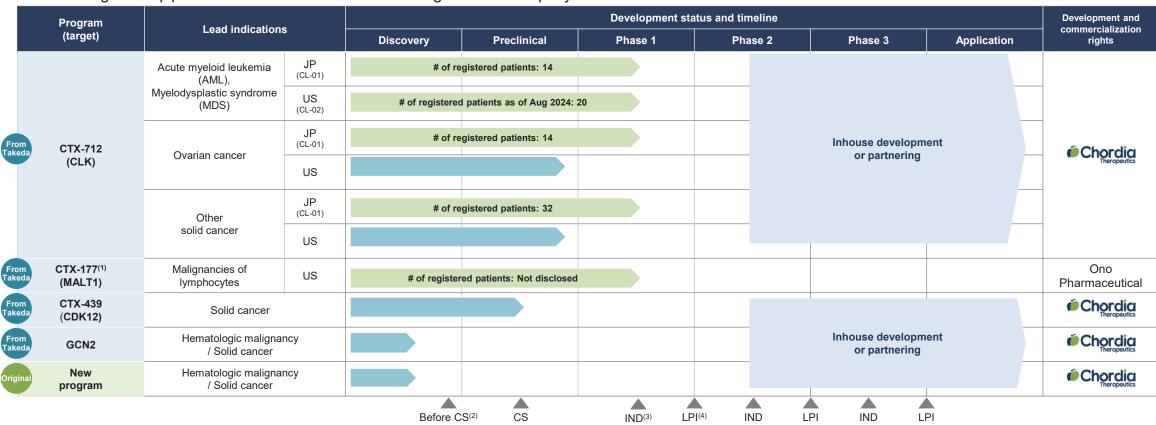
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# Two out of five pipeline assets are in clinical trial stage

#### Chordia is a clinical-stage biotech company with a license-out business model especially outside of Japan

- In addition to 2 clinical assets, preclinical studies are ongoing for one asset
- Progress of pipeline assets is critical for a clinical-stage biotech company



Before clinical stage

Clinical stage

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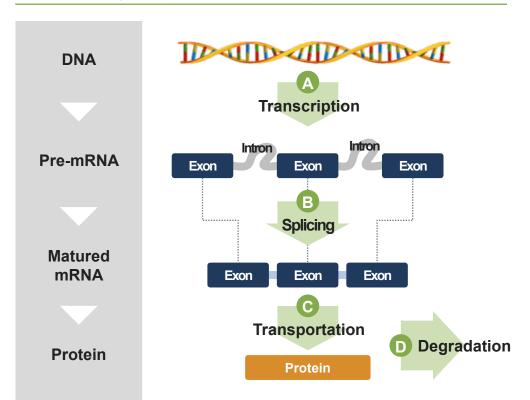
The above information includes forward-looking statements which are based on various assumptions and the beliefs and judgement of the Company's management relying on currently available information, as well as the non-occurrence of various risks. As a result, the Company cannot and does not make any representation or warranties as to the progress, timing or results of any clinical trials or drug approvals. Actual results may vary, potentially materially, from the above forward-looking statements.

<sup>(1)</sup> Unlike CTX-712, CTX-439 and GCN2, the mechanism of action of CTX-177 targets MALT1 inhibition is not related to RNA deregulation stress, (2) Candidate Selection, (3) Investigational New Drug Application, and (4) Last Patient In.

# RNA generation process and pipeline modes of action

• Our pipeline, excluding CTX-177 (MALT1 inhibitor), has a mechanism of action that selectively kills already overloaded cancer cells by placing additional load on the cell for each of the processes that produce RNA.

#### **Process to generate normal RNA and Protein**



#### A: Transcription

Chordia's Pipeline: CTX-439(CDK12 inhibitor)

The process of transcribing DNA information onto mRNA. RNA polymerase is an important protein directly responsible for this transcription process. RNA polymerase uses DNA as a template to produce a Pre-mRNA

#### B: Splicing

Chordia's Pipeline: CTX-712(CLK inhibitor)

Post-transcriptional pre-mRNA contains both intron sequences that are not needed for protein synthesis and exon sequences that are needed to make proteins. The process of joining exon sequences and removing intron sequences to make mature mRNA

#### C: Transportation

Chordia's Pipeline: GCN2 inhibitor

The process of transporting spliced mature mRNAs and transfer RNAs (tRNAs) needed to make proteins to the site of protein synthesis

#### D: Degradation

Chordia's Pipeline: **NEW (Target is undisclosed)** 

The process by which mRNA and tRNA, which serve as templates for protein synthesis, are degraded

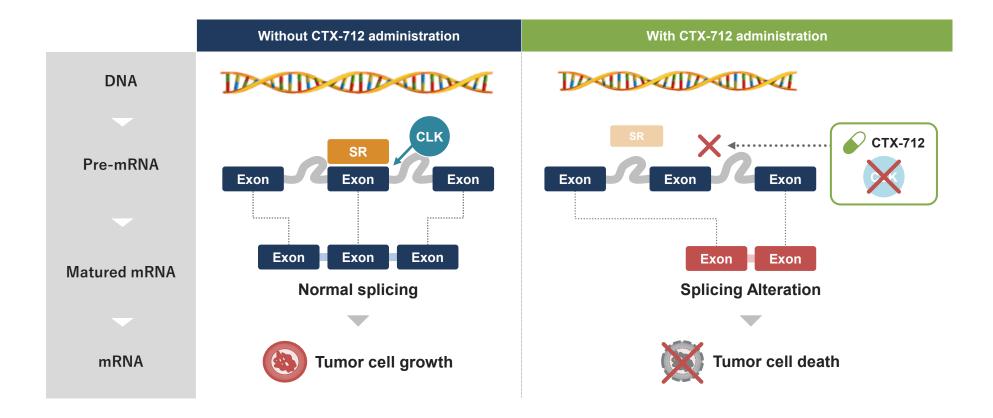
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<sup>\*</sup>For illustrative purposes only.[Prepared by the Company]

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# CTX-712 adds additional RNA deregulation stress to kill cancer

- Splicing is to eliminate unnecessary parts in the mRNA maturation process
- CTX-712 induces splicing alterations and increases RNA deregulation stress resulting in tumor cell death

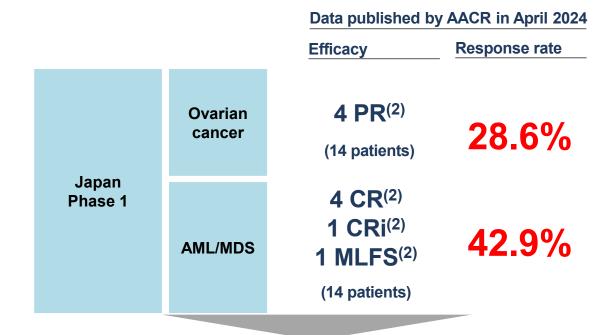


<sup>\*</sup>For illustrative purposes only.[Prepared by the Company]

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# Demonstrated efficacy of CTX-712 in ovarian cancer, AML and MDS

 Anti-tumor efficacies were observed with multiple patients of ovarian cancer, acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) who relapsed or refractory to standard treatment



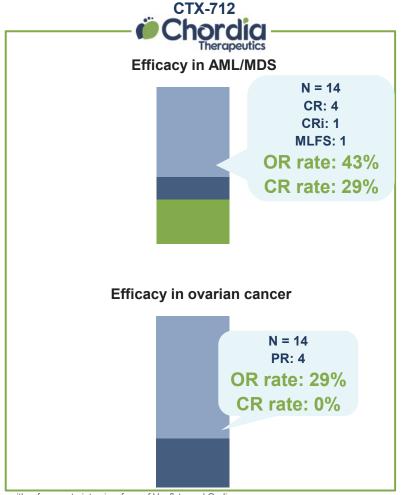
- Prioritize AML as high unmet medical needs exist to pursue NDA submission in 2026~2028<sup>(1)</sup>
- CTX-712 is in Phase 1/2 in US and dosed to 20 AML/MDS patients as of end of August 2024

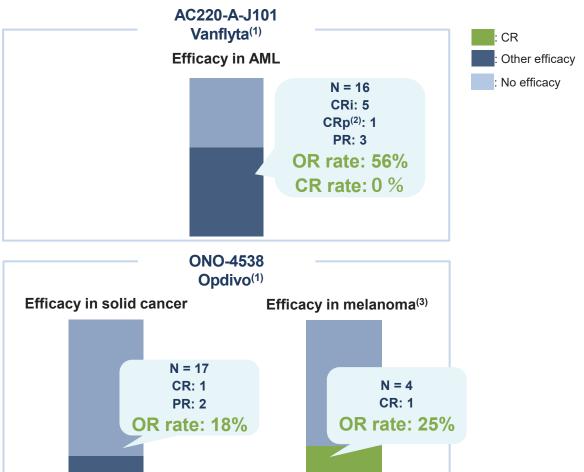
<sup>(1)</sup> The timing of the application for approval is based on the assumption that the clinical data necessary for the application for approval will be collected at the time and in the content as assumed by the Company. If the necessary clinical data cannot be collected as assumed by the Company, or if clinical data is collected but it takes time to submit the application for approval may be submitted after 2027, or the application for approval may not be submitted.

(2) CR: Complete Remission, CRi: Complete remission with incomplete hematologic recovery, MLFS: Morphologic Leukemia Free State, PR: Partial Response

# CTX-712 shows high response rate in Phase 1 clinical trials

• The anti-tumor efficacy of CTX-712 for AML, MDS, and ovarian cancer is comparable to that of an approved drug for AML and a blockbuster drug originating in Japan, respectively, in Phase 1 trials





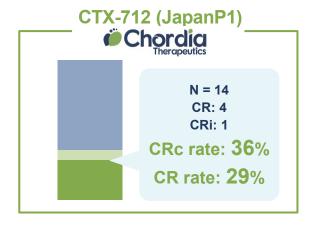
Source: Prepared by the Company with reference to interview form of Vanflyta and Opdivo CR with incomplete platelet recovery
Melanoma was the first disease area for which Opdivo was approved, and the disease area in which Opdivo showed the highest efficacy among the disease areas in which it was initially tested in Phase I trials.

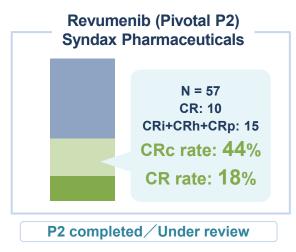
Highly confidential Chordia Therapeutics Inc.

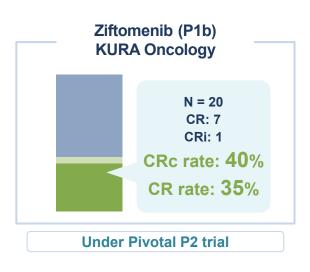
# Comparison with the recent FDA approved and submitted drugs

 Results comparable to those of single-agent therapies approved or submitted for approval. Focus on adding more cases of AML in the U.S.

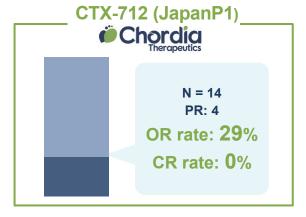
AML

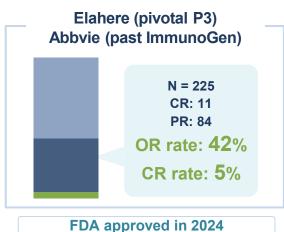














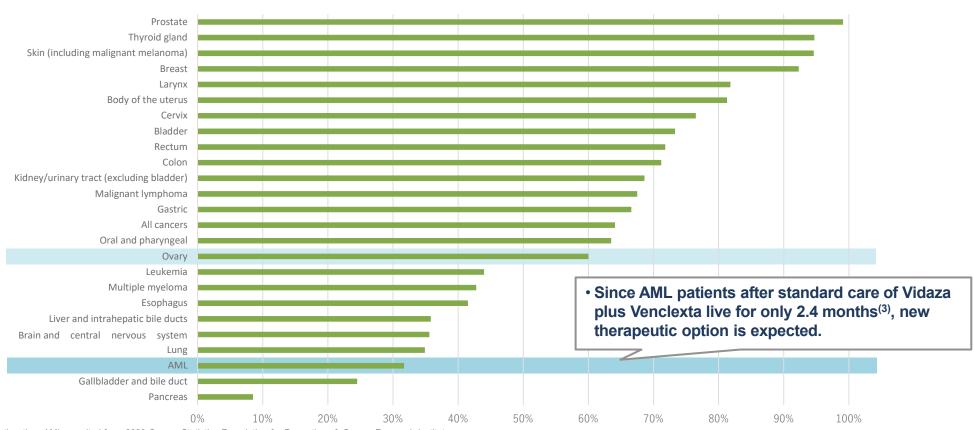
- Our trial is a phase 1 trial and therefore has different assumptions than the Pivotal trial
- Potential exists to coexist with Revumenib, Ziftomenib, and Elahere (approved) with different mechanisms of action to expand the market together (in turn, in use and in cancer patients)



# CTX-712 targets difficult to treat AML and ovarian cancers

• Five years survival rate of AML and ovarian cancer is poor and there exist unmet medical needs. Immuno-oncology therapy is not approved in these indications and new therapeutic options are expected

#### 5-year survival rates



<sup>1)</sup> All of 5-year survival rates other than AML are cited from 2023 Cancer Statistics Foundation for Promotion of Cancer Research Institute

(3) Abhishek Maiti, et. Al. Haematologica. 2021 Mar 1; 106(3): 894–898.

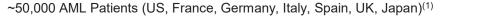
<sup>2) 5-</sup>year survival rates of AML are cited from National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program Leukemia (2013-2019)

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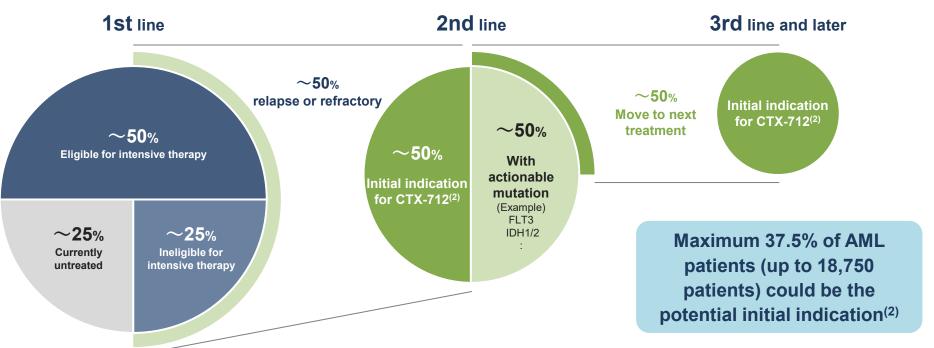
# CTX-712 for 2nd line and later AML patients with limited options

● CTX-712' initial target is relapsed and refractory AML patients (18,750 people) with high unmet medical needs





: Initial target patient population for CTX-712



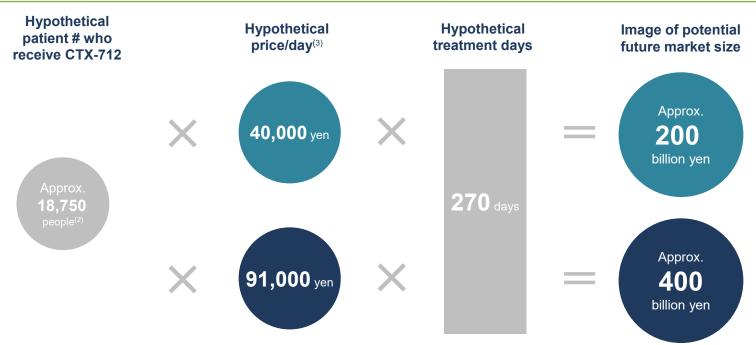
<sup>(1)</sup> Our estimate based on Global Data AML epidemiology forecast to 2029 (Global Data 2020)

<sup>(2)</sup> The Company estimates roughly 50% AML patients receive the 2nd line therapy regardless of the 1st line therapy are potential target patient population for CTX-712.

# Market size of 2nd line and later AML to reach over 200 billion yen

●CTX-712 is expected to initially target second-line AML and later, with high unmet medical needs, and the market size for this application is expected to be more than 200 billion yen<sup>(1)</sup>

#### Market size simulation based on hypothetical assumptions for AML 2nd line<sup>(1)</sup> and later



(4) The Company's estimate based on the median overall survival span in the Global Phase 3 Clinical Study of Xospata, which was 9.3 months

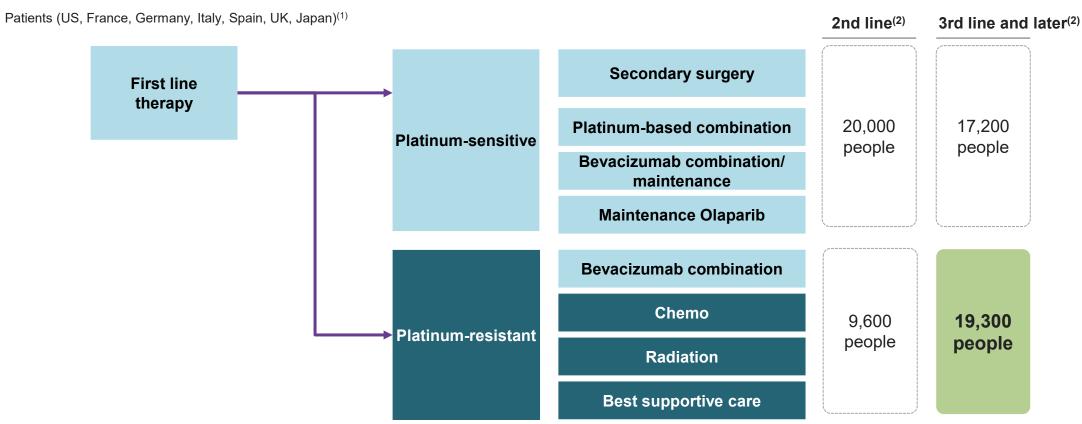
This is an image for estimating the potential market size of CTX-712 as AML 2nd line, and does not represent the objective market size of the Chordia Therapeutics Group business as of Aug 2024. The figures shown in this slide are estimates made by the Company based on external research materials, etc., and their accuracy is subject to the limitations inherent in such research materials, etc., and estimates, and therefore the actual market size may differ significantly from the above estimates
 Cited from P23. The number of patients used in this estimation is the estimated number of patients as of 2029 taken from Global Data 2020

<sup>(3)</sup> Based on the average price of Venclexta in Japan, US and Germany of 285.68\$ /treatment day and the average price of Xospata in Japan, US and Germany of 653.47\$ /treatment day (\$1 =140 yen) based on Global Data 2021

# Limited therapeutic option for platinum-resistant ovarian cancers

•Initial target population is assumed to be patients with relapsed and refractory platinum-resistant with limited treatment beyond third-line therapy

#### Second line and later therapy for ovarian cancer<sup>(1)</sup>



<sup>(1)</sup> Ovarian, Fallopian Tube, and Peritoneal Cancer Treatment Guidelines 2020, the Japan Society of Gynecologic Oncology (jsgo.or.jp)

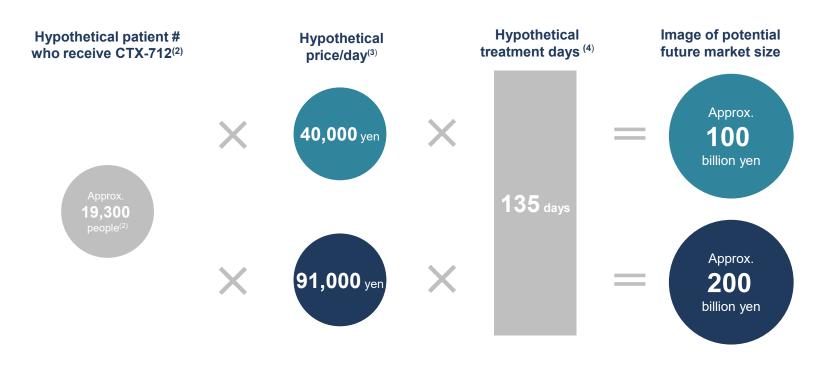
<sup>(2)</sup> Referred to 2028 estimate taken from Global Data 2019. Number of platinum-resistant patients in 3rd line and later was sum of 3rd, 4th, switch over patients

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## Platinum-resistant ovarian cancer drug market to reach 100 billion yen

• The first targeted market of CTX-712 is relapsed and refractory platinum-resistant ovarian cancer patients with high unmet medical needs

#### Estimated market size of 3rd line and later treatments for platinum-resistant ovarian cancer<sup>(1)</sup>



<sup>(1)</sup> This is an image for estimating the potential future market size of CTX-712 as platinum resistant ovarian cancer drug, and does not represent the objective market size of the Chordia Therapeutics Group business as of April 2024. The figures shown in this slide are estimates made by the Company based on external research materials, etc., and their accuracy is subject to the limitations inherent in such research materials, etc., and therefore the actual market size may differ significantly from the above estimates

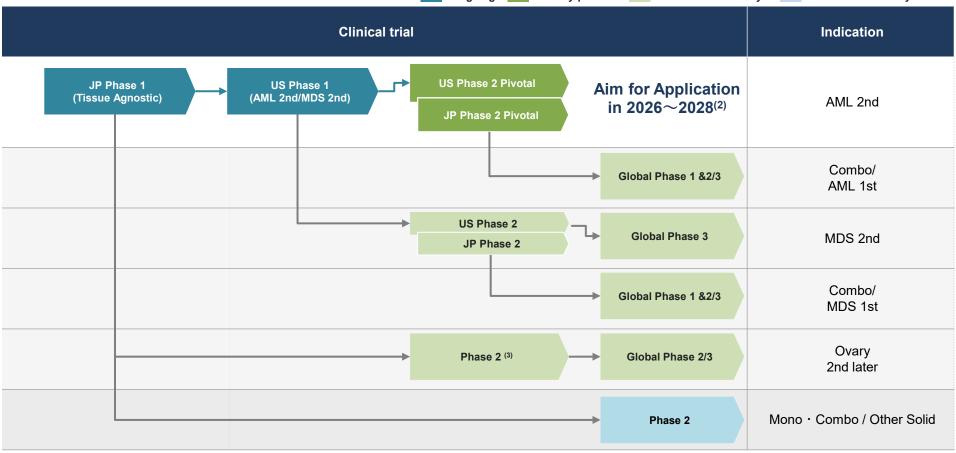
<sup>(2)</sup> Cited from P25. The number of patients used in this estimation is the sum of estimated number of 3rd line. 4th line and 4th line Switch over patients as of 2028 taken from Global Data 2019

 <sup>(3)</sup> Drug price designated as an AML drug is applied based on assumption CTX-712 gets priced in AML first
 (4) The Company's estimate based on the median overall survival for patients who received chemotherapy in 3rd and 4th lines and later (Global Data 2019)

# Medium-term goal of maximizing product value through expansion

• At this moment, our strategy is to focus on AML after the 2nd line, for which clinical evidence has been confirmed, and to aim for conditional early approval. We will aim for value maximization through sequential progress of 1st line treatment for AML and indication expansion for other cancers

• On going • Already planned • With clinical efficacy | Non-clinical efficacy verified



<sup>(1)</sup> Chordia's initial estimate of the largest number of potentially addressable patients based on Global Data 2020 (AML 2nd & 1st is as described on Page 27, MDS 2nd is the sum of 2nd line patients of High Risk MDS, MDS 1st is the sum of 1st line patients of High Risk MDS, and Ovary 2nd later is the sum of 2nd , 3rd , 4th, and 4th Switch Over patients in platinum-resistance), which may differ from the actual number of patients that could be approached,

<sup>(2)</sup> The above information includes forward-looking statements which are based on various assumptions and the beliefs and judgement of the Company's management relying on currently available information, as well as the non-occurrence of various risks. As a result, the Company cannot and does not make any representation or warranties as to the progress, timing or results of any clinical trials or drug approvals. Actual results may vary, potentially materially, from the above forward-looking statements

<sup>(3)</sup> We assume that this portion of the study could be a Pivotal trial in Japan.

# Multi drugs received FDA approval in Phase 2 for AML that is initial indication of CTX-712

• Six of the eight most recently approved drugs have been approved in Phase 2. At this time, SYNDAX and KURA is conducting NDA activities based on Phase 2 results

Status	Line	Target	Drug name	Developing	FDA approval			
Status	LINE	Target		company	Timing	Stage as of approval	Designation	
		BCL-2	VENCLEXTA (venetclax)	AbbVie	2018	Phase 2	Breakthrough Therapy	
	1st line	SMO	DAURISMO (glasdesib)	Pfizer	2018	Phase 2	Priority review policy	
			RYDAPT (midastaurin)	Novartis	2017	Phase 3	Breakthrough Therapy	
Annuovad	2nd and/or later  IDH2  VANFLYTA (quizartinib)  S  IDH16  IDH17  IDH17  IDH17A	FLT3		Astellas	2018	Phase 3 (Top line)	Orphan Drug Fast track	
Approved				Daiichi Sankyo	2019 (Japan Only)	Phase 3	Orphan Drug Fast track	
		IDH1		Start up Company Agios Pharma (Acquired by Servier.)	2019	Phase 2	Fast track	
		Agios Pharm. (Licensed out to BMS)	2017	Phase 2	Orphan Drug Priority review policy			
		CD33	(gemtuzumab	Pfizer	2020	Phase 2	Accelerated drug approval program	

Source: Prepared by the Company with reference to ClinicalTrials.gov

NDA submission<sup>(Note)</sup>

#### **Achievements and future milestones for CTX-712**

Achievemer	nts as of August 2024	Future best-case milestones(Note)			
✓ Q4 2023	CTX-712 last patient enrollment for Japan study	2H 2024	CTX-712 submit application for Orphan drug designation		
✓ Q4 2023	CTX-712 publication regarding US study	2H 2025	CTX-712 publication of clinical data from US study		
✓ Q2 2024	CTX-712 publication of clinical data from Japan study	2H 2025	CTX-712 initiate Phase 2 in US and Japan		
		2026	CTX-712 acquire Phase 2 topline data		
		2026 - 2028	CTX-712 NDA submission in Japan		

						: On going	
CY2023	CY2023 CY2024		CY2025		CY2026		
2H	1H	2H	1H	2H	1H	2H	
Phase 1 of AML/MDS and solid (JP)							
Phase 1 part of AML/MDS(US)							
Phase 2 part of AML study (JP/US) <sup>(Note)</sup>							

(Note) Based on the assumption that the clinical trials will proceed as we expect, and if the necessary clinical data cannot be collected as we expect, or if for some reason the next clinical trial is not conducted or an application for approval is not filed even though the clinical data has been collected, or if it takes time before the next clinical trial is conducted, may be conducted at a different time than stated, or may not be conducted at all.

# **CLK** competitive landscape

#### Competitors targeting CLK Inhibitor (Company View), as of August 31, 2024

Target	Pipeline	Company	Clinical stage
CLK	Cirtuvivint (SM08502)	Biosplice	Phase 1
CLK	BH30236	BlossomHill Therapeutics	Phase 1
CLK	_	Redna Therapeutics	Pre-Clinical

#### **Overview of Biosplice and Cirtuvivint**

- Biosplice (formerly Summed) is San Diego, CA-based clinical stage company. They have multiple CLK programs in oncology, neurology and musculoskeletal indications.<sup>(1)</sup>
- Biosplice published Cirtuvivint Phase 1 data at ESMO 2022. Tumor shrinkage (>10%) seen in 6 subjects as a single agent treatment but no PR/CR.<sup>(2)</sup>
- According to CT.gov, Cirtuvivint is in Ph1b combined with standard-of-care agents in castrate-resistance prostate cancer, colorectal cancer, and non-small cell lung cancer (CT05084859).<sup>(3)</sup>

#### **Overview of BlossomHill Therapeutics**

 BlossomHill Therapeutics is a preclinical-stage, small molecule-focused biotech company based in San Diego, CA that has received a combined \$174M investment from Cormorant Asset Management, OrbiMed, Vivo Capital, Hercules BioVentures Partners LLC, COLT Ventures, and others.<sup>(5)</sup>

#### **Overview of Redona Therapeutics**

- Redona Therapeutics (formerly Twentyeight-Seven) is Watertown, MA-based preclinicalstage biotech company backed by MPM Capital, Longwood Fund and CVCs of Novartis venture fund, J&J Innovation, Vertex Ventures and Astellas venture management.<sup>(4)</sup>
- According to their company web site (https://redonatx.com/pipeline/), Redona has CLK program as their lead program which is in candidate selection stage.

<sup>(1)</sup> BioSplice website, (2) ESMO 2022, #4510, (3) Clinical.gov (4) News release from Redona (September 6, 2018), 5) New release from BlossomHill (Feb 2024)

# **CLK** patent landscape

Substance patent for CTX-712 is already registered in 51 countries all over the world

#### **Asia** (6)

Japan China Hong Kong India South Korea Singapore

#### Americas (3)

USA Brazil Canada

#### EU and Others (42)

Albania Iceland Austria Italy Belgium Liechtenstein Bulgaria Lithuania Switzerland Luxembourg Cyprus Latvia Czech Republic Monaco Germany North Macedonia Denmark Malta Netherlands Estonia Spain Norway **Finland** Poland France Portugal **United Kingdom** Romania Greece Serbia Croatia Sweden Hungary Slovenia Ireland Slovakia

#### San Marino

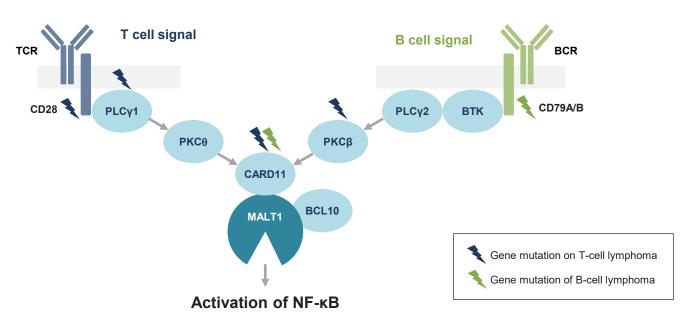
Turkey
Bosnia and Herzegovina
Montenegro
Morocco
Russia

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# Mucosa associated lymphoid tissue protein 1 (MALT1) inhibitor<sup>(1)</sup>

MALT1 activates the transcription factor NFkB. In refractory lymphomas, genetic mutations that activate signals in factors of the T-cell signaling or B-cell signaling pathways (T-cell receptor CD28, B-cell receptor CD79A/B, PLCγ1, PKCβ, CARD11), which in turn activate NF-kB via BTK and MALT1 activation is triggered and the lymphoma grows abnormally

Mode of action



# Indication and characteristics

- MALT1 inhibitors are expected to exhibit antitumor activity as single agents or in combination with other agents in lymphomas with active genetic mutations in the TCR or BCR pathways
- MALT1 inhibitors have the potential to act synergistically with immune checkpoint inhibitors as combination drugs since they have the effect of reducing regulatory T cells, which have been reported to be a factor in immune checkpoint inhibitor unresponsiveness

<sup>\*</sup>For Illustrative purposes only. Prepared by the Company

<sup>(1)</sup> Not related to RNA Deregulation Stress

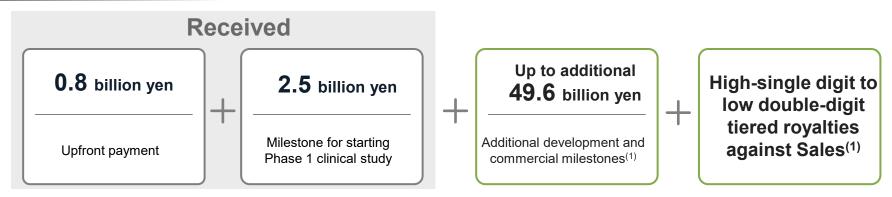
<sup>(2)</sup> Source: J Clin Invest. 2018 Oct 1;128(10):4397-4412. / Clin Cancer Res. 2013 Dec 15;19(24):6662-8

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# Out-license to Ono Pharmaceutical, Opdivo developer for up to 50 billion yen

- ONO-7018 (a.k.a. CTX-177) is in Phase 1 in US (ClinicalTrials.gov Identifier: NCT05515406)
- MALT 1 inhibitor (CTX-177) is expected synergetic efficacy with BTK inhibitors<sup>(2)</sup>

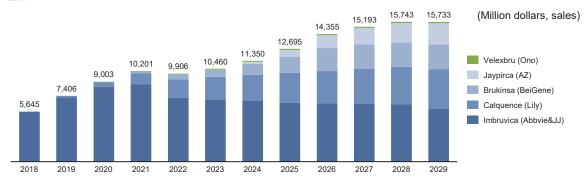
**Licensing conditions with Ono Pharmaceutical** 



#### Status of clinical study of ONO-7018 (CTX-177)

- In August 2022, ONO PHARMA USA, Inc., the U.S. subsidiary of Ono Pharmaceutical Co., Ltd. initiated a Phase 1 study in patients with relapsed or refractory non-Hodgkin lymphoma or chronic lymphocytic leukemia in the U.S.
- In June 2024, Ono presented "A phase I, first-in-human study of ONO-7018 in patients with relapsed/refractory non-Hodgkin lymphoma or chronic lymphocytic leukemia." at American Society of Clinical Oncology (ASCO) 2024

#### Market size of BTK inhibitors for cancer<sup>(3)</sup>



<sup>(1)</sup> The maximum amount of milestone payments and the percentage of royalties that we are entitled to receive as stipulated in the contract entered into between Ono Pharmaceutical Co., Ltd. and the Company. The period during which we can receive royalties is limited to the duration specified in the contract. In order for us to receive the milestones and royalties, the conditions detailed in the contract are not met, we may not be able to receive the maximum amount of the milestones or any at all, or any royalties (2)2022 ASH Presentation abstract # 4000, (3) Cite from Cortellis Analysis Forecast at Clarivate as of April 19, 2024, In addition, the market size of BTK inhibitors expected to be used in combination with CTX-177 is shown, not the market size of CTX-177 or its forecast.

# **Competitive landscape**

#### Competitors for MALT1 inhibitor (the Company's perspective), as of August 31, 2024

Drug	Sponsor	Phase (Start timing)	Indication	Others	URL (ClinicalTrials.gov)
Safimaltib (JNJ-67856633)	Janssen Research & Development, LLC	Phase 1 (April 3, 2019)	Non-Hodgkin's Lymphoma and chronic lymphocytic leukemia	Mono	A Study of JNJ-67856633 in Participants With Non-Hodgkin's Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL) - Full Text View - ClinicalTrials.gov
Safimaltib (JNJ-67856633)	Janssen Research & Development, LLC	Phase 1 (July 28, 2021)	Non-Hodgkin's Lymphoma and chronic lymphocytic leukemia	Combo with Ibrutinib(JNJ-54179060)	A Study of the MALT1 Inhibitor JNJ-67856633 and Ibrutinib in Combination in B-cell NHL and CLL - Full Text View - ClinicalTrials.gov
SGR-1505	Schrödinger	Phase 1 (April 10, 2023)	Matured B cell lymphoma	Mono	Study of SGR-1505 in Mature B-Cell Neoplasms - Full Text View - ClinicalTrials.gov
ABBV-525	AbbVie	Phase 1 (April 4, 2023)	B cell lymphoma	Mono	Study Record   Beta ClinicalTrials.gov

# Conducting eleven cases of collaboration research with academia and industry players

•In addition to joint research to advance specific pipeline research and development, while also utilizing grants from AMED, we are also actively working on new platform development

CTX-712

National Cancer Center Japan CTX-177

Kyoto Univ Miyazaki Univ National Cancer Center Japan CTX-439

Kyoto Univ Tokyo Univ Mie Univ GCN2 inhibitor

**Nagoya City Univ** 

**Platform** 

**Kyoto Univ Fujitsu Limited** 

**Conduct collaboration research** 



#### Participate in research projects funded by AMED as a research partner

CTX-712

Kyoto Univ (research rep)

Nonclinical pipeline

The Univ of Tokyo (research rep)

New pipeline

Kyoto Univ (research rep)

**Platform** 

Kyoto Univ (research rep)

**Platform** 

Kyoto Univ (research rep)

Platform

National Cancer Center Japan (research rep)

# **Patent landscape**

• Strong patent position with substance patent along with process and usage patents

	Application #	Application date	Publication date	Patent #	Registered countries	Substance patent Assignee(s)
	PCT/JP2017/016717	Apr. 28, 2016	Nov. 2, 2017	WO2017/188374	51	Takeda
CTX-712 (CLK inhibitor)	PCT/JP2023/013361	Mar. 31, 2022	Oct. 5, 2023	WO2023/190967	_	Chordia & National Cancer Center Japan
	Japan / 2024-003374 (before PCT)	Jan. 12, 2024	_	_	_	Chordia
	PCT/JP2019/046261	Nov. 28, 2018	Jun. 4, 2020	WO2020/111087	11	Takeda
CTX-177 (MALT1 inhibitor)	PCT/JP2021/019911	May 27, 2020	Dec. 2, 2021	WO2021/241611	_	Takeda
	PCT/JP2023/003154	Feb. 2, 2022	Aug. 10, 2023	WO2023/149450	_	Chordia & Ono
CTX-439 (CDK12 inhibitor)	PCT/JP2019/013531	Mar. 29, 2018	Oct. 3, 2019	WO2019/189555	4 and 1 region	Takeda
(GCN2 inhibitor)	PCT/JP2017/028928	Aug. 10, 2016	Feb. 15, 2018	WO2018/030466	6	Takeda

# **Agenda**

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# Financial results summary

FY 8/2024 financial results

# No business revenue due to CTX-177 milestone income and other pipelines not yet licensed out

- Business revenues did not generate revenues from the out-licensing of MALT1 inhibitor CTX-177 and other pipelines
- By focusing on accelerating clinical trials of the CLK inhibitor CTX-712 and bringing other pipeline research in-house, research and development expenses for FY2023 are expected to be 1.5 billion yen, down 0.4 billion yen YoY(-0.4 billion yen compared to budget)
- Estimated net loss of 1.8 billion yen

FY 8/2025 financial forecasts

# No specific plans for milestones and out-licensing of other pipeline products in CTX-177, a MALT1 inhibitor, and do not anticipate any revenues

- Revenues from out-licensing of CTX-177, a MALT1 inhibitor, and other pipeline products are not expected at this
  moment. However, the Company is actively engaged in various out-licensing activities and expects to disclose
  information when appropriate
- Research and development expenses are expected to be 2.0 billion yen, up 0.5 billion yen YoY, as the Company will
  continue to focus on the U.S. clinical trials of CTX-712, a CLK inhibitor, while other pipelines will focus on value-adding
  activities using internal resources
- Estimated net loss of 2.3 billion yen

# FY 8/2024 Financial results (balance sheet)

• Financial results for the period remain almost unchanged with ordinary loss offset by listing in June 2024

Unit:	Mil	lion	yer

	FY 8/2023 (Actual)	FY 8/2024 (Actual)	Change
Current assets	4,891	4,605	-286
Cash and deposits	4,799	4,329	-469
Non-current assets	17	26	+9
Total assets	4,909	4,632	-276
Current liabilities	408	471	+62
Non-current liabilities	0	0	0
Total liabilities	408	471	+62
Total net assets	4,500	4,161	-339
Total liabilities and net assets	4,909	4,632	-276

#### **Key for FY2023**

#### • Current assets and net assets:

 Cash and deposits and net assets: Decrease due to ordinary loss for the period was offset by capital increase through third-party allotment upon listing.

#### • Current liabilities:

 Income taxes payable: Increase in income taxes payable (factor-based tax) due to increase in capital stock from the capital increase

# FY 8/2024 Financial results (profit and loss)

● The Company has turned to a loss due to the absence of milestone income from Ono Pharmaceutical Co., Ltd. recorded in FY2023. Research and development expenses remained almost flat due to compression of other costs, despite an increase in CTX-712 clinical trials

	FY 8/2023 (Actual)	FY 8/2024 (Actual)	Change
Revenue	2,500	-	- 2,500
Direct expenses	0	0	0
Research and development expenses	1,996	1,499	- 497
CTX-712	686	1,018	+ 331
CTX-177	3	0	- 2
CTX-439	616	132	- 483
Other (including personnel expenses)	690	347	- 342
Other administrative expenses	291	301	+ 10
Operating profit (loss)	212	(1,801)	- 2,013
Non-operating income	26	17	- 8
Non-operating expenses	12	41	+ 28
Profit (loss) before income taxes	225	(1,824)	- 2,050
Income taxes	2	2	+ 0
Profit (loss)	223	(1,827)	- 2,050

#### **Key for FY2023**

#### • CTX-712 (CLK):

- .Completion of patient enrollment for Phase 1 clinical trial in Japan (46 cases of solid tumors, 14 cases of hematologic malignancies)
- In the Phase 1/2 clinical trial in the United States, 20 cases were added

#### • CTX-177 (MALT1):

 Ono Pharmaceutical Co., Ltd. presented an overview of the U.S. trial at the American Society of Clinical Oncology (ASCO) in June 2024

#### • CTX-439 (CDK12):

 Having completed safety tests and the manufacturing of the investigational drug for the start of the clinical trial, preparations for the next phase are underway

## FY 8/2025 Financial forecasts

• Assumption is that the highest priority will be placed on advancing the CTX-712 clinical trial. We expect to respond to cost fluctuations depending on the progress in patient enrollment and negotiations with the regulatory authorities as appropriate

Unit: Million yen

	FY 8/2024 (Actual)	FY 8/2025 (Plan)	Change
Revenue	-	-	-
Direct expenses	0	0	0
Research and development expenses	1,499	2,025	+ 525
CTX-712	1,018	1,610	+ 592
CTX-177	1	0	- 0
CTX-439	132	18	- 114
Others (including personnel expenses)	347	396	+ 49
Other administrative expenses	301	408	+ 107
Operating profit (loss)	(1,801)	(2,434)	- 633
Non-operating income	18	56	+ 38
Non-operating expenses	41	0	- 41
Profit (loss) before income taxes	(1,824)	(2,378)	- 553
Income taxes	2	2	0
Profit (loss)	(1,827)	(2,380)	- 553

#### R&D Plan for FY2024

#### • CTX-712 (CLK):

- Completion of Phase I clinical trials in Japan
- Conduct the Phase I part of a Phase I/II clinical trial in the U.S. and plan to present the interim data at a prestigious international conference.

#### • CTX-177 (MALT1):

Ono Pharmaceutical Co., Ltd. will bear all costs and continue the clinical trial.

#### • CTX-439 (CDK12):

• Other outsourced research funds are assumed to be used only for activities subsidized by AMED.

#### Other administration cost:

Registration of European patents

#### • (Reference) Non-operating income:

 Assumption that a total of 5 grants from AMED will be sub-commissioned

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# Steady progress in both R&D and corporate activities <FY 8/2023>

R&D

CTX-712

Japan

Phase 1 clinical trial

Total 60 patients enrollment completed

Phase 1 clinical trial results for all patients

Apr 2024 publication at AACR

**Overseas** 

Phase 1/2 clinical trial # of patients

 $\boldsymbol{3} \rightarrow \boldsymbol{20}$ 

\*Compared to Aug 2023

**CTX-177** 

**Overseas** 

Overview of Phase 1 clinical trial

Ono Pharmaceutical published at ASCO 2024

### **Corporate activities**

Listed on Growth market of Tokyo Stock Exchange \*June 2024

Received Minister of Education, Culture, Sports, Science and Technology (MEXT) Award at Nippon Startup Award 2024

# Prioritized business goals for FY 8/2024

- Clinical trial progress for approval of CTX-712 (CLK inhibitor)
- Submission for orphan drug designation
- Determination of international non-priority names (by WHO)
- Solid progress of clinical trial
- Prepare Interim report on the first part of the Phase 1/2 clinical trial in the U.S. at a prestigious international conference

- Proactively engage in new business alliances
- In addition to CTX-712, we will explore the possibility of a business alliance for CTX-439, GCN2, and if we can obtain good economic terms, we will build a relationship with a view to an early agreement
- Constantly communicate on our business alliances and expect to make appropriate disclosures once finalized

Properly execute disclosure to shareholders

- Disclose research progress through presentations at national and international conferences, with at least one presentation at a conference per year
- Recognize communication with shareholders and investors as an important matter, hold seminars for investors, and actively communicate the CEO's message in the media

## Management policies and 2030 vision

# Building a world where tomorrow is another day!

Delivering the world's first made-in-Japan new anticancer drugs to patients as soon as possible

----- Mission -----

We are passionate to deliver first-in-class cancer drugs to patients.

—— 2030 Vision ——

To be an R&D-oriented pharmaceutical company based in Japan.

# Our disclosure policy

- Chordia will release information only after receiving permission from the academic societies for the presentation of data, etc., and will disclose information appropriately
- Based on fair disclosure, Chordia will not respond to individual questions
- Chordia will promptly provide answers to all received questions through IR and update the "IR Frequently Asked Questions" page on our website in a timely manner

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