

This press release is an English translation of a Japanese-language press release. The official language of this press release is Japanese, and the Japanese version takes precedence over the English version in terms of content and interpretation.

<Press Release>
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Notice regarding the Publication of the Revised Clinical Trial Protocol **Summary for rogocekib**

Kanagawa Japan

24th September 2025 –Chordia Therapeutics Inc. (Head Office: Fujisawa City, Kanagawa Prefecture; CEO: Hiroshi Miyake, “Chordia”) is currently conducting a Phase 1/2 clinical trial in the United States of the CLK inhibitor rogocekib (development code: CTX-712) targeting patients with relapsed or refractory acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). As announced in the press release dated September 5, 2025, titled “Notice Regarding the Issuance of the 9th Series of Stock Acquisition Rights (with Clause for Exercise Price Adjustment) and the 10th and 11th Series of Stock Acquisition Rights through Third-Party Allotment,” Chordia has revised the clinical trial protocol in response to Project Optimus proposed by the U.S. Food and Drug Administration (FDA). The revised protocol summary has now been published on ClinicalTrials.gov, one of the world’s largest clinical trial databases: <https://clinicaltrials.gov/> (NCT05732103).

Summary

- In the dose-escalation cohort, a new twice-weekly dosing schedule has been added to the originally planned once-weekly schedule, with three dose levels (60, 80, and 100 mg) included.
- In the expansion cohort, approximately 60–70 patients are expected to be enrolled to compare multiple doses and regimens.
- A drug-drug interaction study has been added to determine the appropriate dose of rogocekib when co-administered with antifungal agents that inhibit CYP3A enzyme activity.
- As a result of these revisions, the total number of patients to be enrolled in the study has increased from the originally planned 170 to 225.
- Two new clinical trial sites have been added, bringing the total to six.

These protocol revisions aim to optimize dosing for patients to enhance both safety and efficacy, reflecting our efforts to pursue a thoughtful and impactful development path. Although the interim data presentation at a international conference has been rescheduled from the second half of 2025 to mid-2026, patient enrollment is progressing steadily. As of the end of August 2025, a total of 36 patients have been enrolled, and evaluation of the highest dose 100 mg in the twice-weekly schedule is thoroughly underway. Chordia plans to initiate the expansion cohort in early 2026 and is actively expanding trial sites to accelerate enrollment. These efforts are expected to support faster progress in the next phase of development.

Chordia is committed to delivering rogocekib to patients worldwide as quickly as possible, and is focusing internal resources on its development. Chordia also aims to obtain regulatory approval and bring the product to market by ourselves, enhancing its value as a pharmaceutical company.

About AML and MDS

AML (Acute Myeloid Leukemia) and MDS (Myelodysplastic Syndromes) are types of hematological malignancies characterized by abnormal proliferation of white blood cells and other blood cells in the bone marrow, leading to impaired production of normal blood cells. AML, in particular, has poor prognosis and effective treatment options are limited in the second-line setting, representing a high unmet medical need.

About Project Optimus

Project Optimus is a guidance proposed by the FDA in recent years to optimize dose selection in oncology drug development. It was introduced in response to cases where approved doses of anticancer drugs were difficult to continue due to toxicity and tolerability issues. The guidance recommends evaluating multiple doses and regimens from the early stages of development.

About CLK inhibitor rogocekib (development code: CTX-712)

rogocekib is a first-in-class, selective, orally available small molecule inhibitor targeting CDC2-like kinase (CLK), a key regulator of RNA splicing involved in cell proliferation. It has received Orphan Drug Designation (ODD) from the FDA for the treatment of AML and is currently undergoing a Phase 1/2 clinical trial in the United States.

About Chordia Therapeutics

Chordia's lead asset, rogocekib (CLK inhibitor CTX-712), is under Phase 1/2 clinical study in the US. Rogocekib potentially targets the vulnerability of cancer and is expected to deliver benefits to patients of various types of cancer. In addition to rogocekib, Chordia is engaged in the research and development of several assets, including CTX-177, a MALT1 inhibitor, CTX-439, a CDK12 inhibitor, and GCN2 inhibitors. For more information, please visit our website

<https://www.chorditherapeutics.com/en/>.