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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Chordia Therapeutics Publishes First-in-Human Phase 1 Results of CLK Inhibitor Rogocekib for Solid Tumors in *Clinical Cancer Research*

Chordia Therapeutics Inc (Head Office: Fujisawa City, Kanagawa Prefecture; CEO: Hiroshi Miyake, "Chordia") today announced that the final results of the solid tumor part (the "Results") of the first-in-human Phase 1 clinical trial of the CLK inhibitor rogocekib (CTX-712) conducted in Japan (jRCT2080224127) (the "Phase 1 Trial") have been published in *Clinical Cancer Research*.

Clinical data from the Phase 1 Trial of rogocekib in patients with advanced, relapsed, or refractory solid tumors demonstrated manageable safety and signs of efficacy, consistent with the previously reported results from the hematologic malignancy part (announced on October 14, 2025: "Chordia Therapeutics Publishes Phase 1 Results of CLK Inhibitor Rogocekib for R/R AML/HR-MDS in *Blood Advances*"). Partial responses (PR) were observed in patients with ovarian cancer among the solid tumor cohort. In addition, MYC gene amplification, which has been reported to induce RNA regulatory stress, was identified in some of these responding cases, suggesting that MYC amplification may serve as a biomarker for patient stratification.

Rogocekib is currently being evaluated for safety and efficacy in an ongoing Phase 1/2 clinical trial in the United States in patients with acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). Chordia believes that these Results support the potential future expansion of rogocekib into solid tumor indications, including ovarian cancer.

Key Highlights

- In the Phase 1 clinical trial, dose-dependent pharmacokinetics (PK) and target engagement as assessed by pharmacodynamic (PD) markers were confirmed. The safety profile was generally manageable.
- Partial responses (PR) were observed in patients with ovarian cancer who were refractory to standard therapies or had limited treatment options. Although the number of cases was limited, prolonged survival was suggested in patients with MYC gene amplification.

Summary

Rogocekib is a novel, orally available small-molecule inhibitor that selectively targets CDC2-like kinase (CLK), a key regulator of RNA splicing. A Phase 1 trial conducted in Japan in patients with advanced, relapsed, or refractory solid tumors was designed to evaluate safety, tolerability, maximum tolerated dose (MTD), pharmacokinetics (PK), pharmacodynamics (PD), and preliminary antitumor activity.

In this study, rogocekib was administered with stepwise dose escalation on a twice-weekly (BIW) schedule, along with an initial evaluation of a once-weekly (QW) regimen, in 46 patients total with solid tumors. The MTD was determined to be 140 mg BIW. The main treatment-related adverse events were gastrointestinal events, including nausea, vomiting, and diarrhea; these were generally manageable and tolerable overall.

PK analysis demonstrated dose-dependent increases in exposure, and PD analysis showed target engagement through clear inhibition of CLK in humans, as evidenced by changes in RNA splicing in blood cells. In addition, partial responses (PR) were observed in three patients with ovarian cancer, including two cases with MYC gene amplification, suggesting potential antitumor activity in tumors with specific molecular backgrounds.

Publication Details

Phase I Study of Rogocekib in Patients with Advanced, Relapsed, or Refractory Malignant Solid Tumors

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URL:https://aacrjournals.org/clincancerres/article/doi/10.1158/1078-0432.CCR-25-4896/784467/Phase-I-Study-of-Rogocekib-in-Patients-with

About the Journal

Clinical Cancer Research is a peer-reviewed scientific journal that publishes high-quality clinical and translational cancer research bridging basic science and clinical practice. The journal places particular emphasis on clinical studies evaluating novel therapeutic approaches, supported by pharmacological analyses, molecular characterization, and biomarker research to predict treatment response and resistance. It also covers a broad range of innovative research areas that contribute to advances in cancer treatment and clinical research, including precision medicine, molecularly targeted therapies, and immuno-oncology.

About the Phase 1 Clinical Trial (jRCT2080224127)

This first-in-human Phase 1 clinical trial of rogocekib was conducted in Japan from 2018 to 2024 in patients with advanced, relapsed, or refractory solid tumors and hematologic malignancies, with the objective of evaluating safety, tolerability, maximum tolerated dose (MTD), pharmacokinetics (PK), pharmacodynamics (PD), and preliminary antitumor activity.

The study initially included a dose-escalation cohort in patients with solid tumors, in which rogocekib was administered twice weekly (BIW) at doses ranging from 10 mg to 175 mg. This was followed by expansion cohorts in solid tumors evaluating 70 mg or 105 mg BIW, as well as 105 mg once weekly (QW). In parallel with the solid tumor expansion cohorts, patients with hematologic malignancies were treated with 70 mg or 105 mg BIW.

Glossary of Terms

Term	Explanation
AML	Abbreviation for Acute Myeloid Leukemia, a hematologic malignancy characterized by the clonal proliferation of myeloid precursor cells in the bone marrow.
CLK	Abbreviation for CDC2-Like Kinase, an enzyme that catalyzes the transfer of phosphate groups to target proteins and plays an important role in splicing.
Dose-escalation cohort	A group of patients in a Phase 1 clinical trial in which doses gradually increased from a low starting level to evaluate safety and tolerability.
Expansion cohorts	Additional groups of patients enrolled after safety have been confirmed in the dose-escalation study to further evaluate safety and efficacy at specific doses or in defined patient populations.
MDS	Abbreviation for Myelodysplastic Syndrome, a hematologic malignancy characterized by dysfunctional hematopoietic stem cells in the bone marrow, resulting in ineffective hematopoiesis and a deficiency of normal blood cells.
MTD	Abbreviation for Maximum Tolerated Dose, the highest dose of a drug that can be administered in a clinical trial without causing unacceptable adverse effects.
MYC	A well-known cancer-associated gene involved in tumor cell proliferation and survival.
Partial response (PR)	A reduction in tumor size meeting established international criteria (e.g., RECIST), with the effect maintained for a defined period.
Pharmacodynamic (PD)	A measure of the biological effects of a drug in the body and the extent to which it engages its target molecules.
Pharmacokinetics (PK)	An assessment of how a drug is absorbed, distributed, metabolized, and excreted in the body over time.
RNA regulatory stress	A condition in which excessive stress is placed on the processes of RNA production and processing (e.g., RNA splicing) within cells, disrupting normal RNA function.

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.chordiatherapeutics.com/en/.