Chordia Therapeutics Inc.
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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>
January 10, 2025

Company: Chordia Therapeutics, Inc
Representative: Chief Executive Officer Hiroshi Miyake
(Security Code: 190A TSE Growth Market)
Contact: Chief Financial Officer Kentaro Kume

Rogocekib for the treatment of Refractory or Relapsed Acute Myologic Lymphoma (AML) has been granted Orphan Drug Designation (ODD) in the US by the Food and Drug Administration (FDA)

Kanagawa Japan
January 10, 2024 – Chordia Therapeutics K.K. (Head Office: Fujisawa City, Kanagawa Prefecture; Chief Executive Officer: Hiroshi Miyake) announced that Chordia received Orphan Drug Designation (ODD) in the US by the Food and Drug for rogocekib, which is developing for Refractory or Relapsed Acute Myologic Lymphoma (AML) .

The ODD is based on the Orphan Disease Act of 1983 and is a system for designating drugs that meet certain conditions, such as having fewer than 200,000 patients in the United States and being particularly in need of medical treatment. This system supports and promotes the development of orphan drugs with the aim of providing safe, high-quality drugs to the medical community as soon as possible, considering the situation where research and development of orphan drugs are not progressing sufficiently due to the small number of patients despite the high medical need for such drug.

This designation makes it possible to utilize various pharmaceutical and research cost support measures from the FDA, such as exemption from application fees for new drug applications in the US, reductions or exemptions from federal taxes related to clinical development, as well as preferential measures for development and promotion in the US, and after approval, it will be granted exclusive first-to-market sales rights in the US for seven years, which could be a significant step towards future commercialization of rogocekib. There is no impact on business performance.

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

Rogocekib is a first-in-class, selective, oral, small molecule inhibitor of CDC2-like kinase (CLK), a key regulator of the RNA splicing response that plays an important role in cell proliferation.
We are currently conducting Phase 1/2 clinical trials in the U.S. For details of the U.S. Phase 1/2 clinical trial, please visit clinicaltrials.gov/ (NCT05732103).

About Chordia Therapeutics

Chordia is a clinical stage biotech company based in Fujisawa, Kanagawa Prefecture, Japan, engaged in the research and development of novel therapies for cancers.
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 of several preclinical assets, including CTX-439, a CDK12 inhibitor, which is expected to be effective in cancers with specific abnormalities, as well as GCN2 inhibitors. For more information, please contact our website https://www.chordiatherapeutics.com/en/.