May 23, 2025
J-Pharma Co., Ltd.

Positive Response Received from U.S. FDA at CMC Type-C Meeting for Novel Anticancer Candidate Drug *Nanvuranlat* – Important progress toward the start of Phase III Clinical Trial in the U.S.

J-Pharma Co., Ltd. is pleased to announce that it held a CMC (Chemistry, Manufacturing, and Controls) Type-C meeting with the U.S. Food and Drug Administration (FDA) regarding its novel anticancer drug under development, *nanvuranlat*, and received a positive response in writing from the U.S. FDA on May 13, 2025.

Many pharmaceutical companies request a Type-C meeting with the FDA prior to initiating Phase 3 clinical trials to determine whether the CMC for Phase 3 trials and commercial scale production of the drug substance and drug product meets the FDA's high standards for regulatory review, and only with the FDA's concurrence do they initiate Phase III trials.

The positive response from the FDA indicates that the FDA agrees that *nanvuranlat* meets the quality criteria for commercial scale production, which is a very important milestone for the Company as it moves toward approval in 2030 and initiation of the Phase 3 clinical trial this year. We will continue to accelerate the global development of *nanvuranlat* to bring a new treatment option to patients with refractory cancer.

Type-C Meetings

Type-C meetings are a type of formal consultation that the U.S. FDA conducts with applicants during the drug development process, and are designed to provide a flexible forum for the exchange of views on technical issues related to clinical development and regulatory strategy, including chemistry, manufacturing, and controls (CMC), that are not covered in Type-A, B, D, or INTERACT meetings.

Reference: FDA “Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products” Guidance for Industry
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-pdufa-products

Reference Information

About Nanvuranlat

Nanvuranlat is a novel small-molecule compound independently discovered by J-Pharma that selectively inhibits LAT1. Since 2015, J-Pharma has conducted Phase 1 clinical trial targeting multiple solid tumors and identified its potential in treating biliary tract cancer. From 2018, the Company carried out a Japan based Phase 2 trial over three and a half years, targeting advanced biliary tract cancer, and demonstrated significant clinical efficacy as a monotherapy. Nanvuranlat is the first compound in the world targeting LAT1 in clinical development, and if approved as a pharmaceutical product, it will be a first-in-class drug, offering a groundbreaking mechanism of action for the disease. Nanvuranlat was designated as an Orphan Drug by the U.S. Food and Drug Administration (FDA) in April 2022. This designation grants several benefits, including consultation for clinical development programs, tax credits for clinical trial costs, exemption from application fees, and seven years of market exclusivity in the United States. On September 25, 2024, the FDA approved the Investigational New Drug (IND) application for nanvuranlat for cancer patients.

*Publication on the results of the nanvuranlat

Phase 2 study in Japan Furuse et al. A Phase 2 Placebo-Controlled Study of the Effect and Safety of nanvuranlat in Patients with Advanced Biliary Tract Cancers Previously Clin Cancer Res. 2024; 30(18):3990-3995.

About J-Pharma Co., Ltd.

J-Pharma Co., Ltd. aims to "pursue new possibilities for SLC transporters and contribute to the health and hope of people worldwide through the development of innovative new drugs that address unmet medical needs." Under this mission, the Company has focused on LAT1 (L-type amino acid transporter 1), one of the SLC transporters discovered by the Company's founder and is advancing the development of LAT1 inhibitors to address the needs of patients with cancer and autoimmune diseases, where existing drugs are insufficient. Currently, J-Pharma is conducting clinical development for LAT1 inhibitors such as "nanvuranlat" and "JPH034," and is also advancing research on new candidate compounds. In October 2023, the Company established a U.S. subsidiary and is closely collaborating with involved organizations and U.S. consultants to develop appropriate regulatory, development, and intellectual property strategies.

For more information about J-Pharma, please visit https://www.j-pharma.com/en/.

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