June 10, 2025
J-Pharma Co., Ltd.

BREAKFAST MEETING for Prospective Investigators during ASCO ~First Step to Start U.S. Phase 3 Clinical Trial of LAT1 Inhibitor *NANVURANLAT* for Advanced Biliary Tract Cancer~

J-Pharma Co., Ltd. announces that the company held a Breakfast Meeting for potential principal investigators for *Nanvuranlat,* a novel anti-cancer drug under development, as the first step toward initiating a U.S. Phase 3 clinical trial of *Nanvuranlat*, an L-type amino acid transporter 1 (LAT1) inhibitor for advanced biliary tract cancer, during ASCO 2025 (American Society of Clinical Oncology Annual Meeting) held in Chicago, USA on Sunday, June 1, 2025.

The breakfast meeting was attended by 20 participants from major medical institutions in the U.S., including investigator candidates and contract research organizations (CROs), and a lively Q&A session was held on protocol review, schedule to start the trial, and other topics.

Dr. Junji Furuse, President of the Kanagawa Cancer Center, the principal investigator of the Phase 2 clinical trial, attended as an advisor and provided valuable insights based on the results of the trials conducted in Japan.

Lively discussion at the Breakfast Meeting

Comments from Dr. Junji Furuse, President of the Kanagawa Cancer Center

Nanvuranlat (JPH203) is the first-in-class agent that inhibits amino acid uptake in cancer cells, representing an unprecedented mechanism of action. Its clinical introduction is highly anticipated. In the Phase 1 trial, promising results were observed in patients with biliary tract cancer. Furthermore, a randomized Phase 2 trial targeting patients with advanced biliary tract cancer—who currently lack effective treatment options—suggested its potential for the efficacy. A pivotal trial evaluating overall survival is scheduled to begin in the United States, with Japan expected to participate at a later stage. It has been 11 years since the initiation of the Phase 1 trial of JPH203, and the goal is finally coming into view. I truly hope that *Nanvuranlat* will mark a new chapter in the history of biliary tract cancer treatment and contribute significantly to improving patient outcomes."

Comments by Masuhiro Yoshitake, President & CEO:

It has been a great challenge for us, however at the same time we are very proud of the fact that a Japanese bio-venture company has been able to independently promote large-scale clinical trials overseas. I would like to express my sincere gratitude to the medical professionals and patients who have supported us along the way, to all those involved in this project, to our employees who have worked tirelessly day in and day out, and to our stakeholders who have shared our aspirations and supported us from a long-term perspective. We will continue to move forward steadily with clinical development toward the successful completion of Phase 3 clinical trials with the aim of obtaining global approval in 2030.

(Reference)

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 bile duct cancer. From 2018 the company carried out a Japan based Phase 2 trial over three years and half years, targeting advanced bile duct cancer, and demonstrating 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 the first-in-class drug offering a groundbreaking mechanism of action for the disease. *Nanvuranlat* was also 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 and the company is continuing discussions with the FDA in preparation for a Phase 3 trial in the U.S. slated for 2025.

Publication of 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.

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J-Pharma Co., Ltd. aims to "pursue new possibilities for SLC transporters and contribute to the hope and health of people worldwide though 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 in the U.S. consultants to develop appropriate regulatory, development, and intellectual property strategies.
For more information about J-Pharma Co., Ltd., please visit https://www.j-pharma.com/en/

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