December 19, 2025
J-Pharma Co., Ltd.

Nanvuranlat Beacon-BTC Global Phase III Clinical Trial Commences with First Site Activation

We are pleased to announce the successful completion of site activation at the first clinical trial site in the Beacon-BTC global Phase III clinical trial of *nanvuranlat*, an L-type amino acid transporter 1 (LAT1) inhibitor, for the treatment of advanced biliary tract cancer.

The on-schedule activation at the first study site represents an important initial milestone for the Beacon-BTC trial. This achievement was made possible through close collaboration and careful operational execution by the clinical site, healthcare professionals, the contract research organization, and all internal and external partners involved. We would also like to express our sincere appreciation to our stakeholders for their continued support and shared commitment to our long-term vision.

About Global Phase III Clinical Trial (Study Name: Beacon-BTC)

The name “Beacon-BTC” was chosen in the hope that this study will serve as a beacon of hope for patients with biliary tract cancer (BTC)

Beacon-BTC aims to evaluate the efficacy and safety of our investigational product, nanvuranlat, in patients with BTC receiving second-line therapy, for whom treatment

options remain extremely limited. The study consists of two parts, with overall survival (OS) as the primary endpoint.

In Part A, approximately 30 patients per group will be enrolled to compare three *nanvuranlat* dosing regimens with Physician's Best Choice* (PBC) in order to determine the optimal dose. In Part B, approximately 180 patients per group will be enrolled to compare the selected *nanvuranlat* regimen with PBC.

* Physician's Best Choice (PBC) refers to a treatment selected by the physician from among currently approved standard therapies or commonly used regimens deemed appropriate for each patient. In this trial, the options are FOLFOX therapy, FOLFIRI therapy, or best supportive care.

About *Nanvuranlat*

Nanvuranlat is a novel LAT1-selective inhibitor originally discovered by J-Pharma and is the first small-molecule compound of its kind to be clinically developed worldwide. If approved as a pharmaceutical product, it has the potential to become a first-in-class drug with a novel mechanism of action for its target disease.
Since 2015, J-Pharma has conducted Phase 1 clinical studies in multiple solid tumors and identified its potential for the treatment of advanced biliary tract cancer. A Phase 2 clinical study targeting advanced biliary tract cancer was conducted starting in 2018, demonstrating that *nanvuranlat* monotherapy provides clinically meaningful benefit. *
Nanvuranlat was designated as an orphan drug by the U.S. Food and Drug Administration (FDA) in April 2022. Furthermore, on September 25, 2024, the FDA approved the Investigational New Drug (IND) application for clinical studies in cancer patients. In addition, in May 2025, J-Pharma confirmed that the Chemistry, Manufacturing, and Controls (CMC) at the commercial manufacturing scale meet the quality standards required by the FDA.

* Publication on the results of the Japan Phase II clinical study of *Nanvuranlat*:
Furuse et al. A Phase II Placebo-Controlled Study of the Effect and Safety of *Nanvuranlat* in Patients with Advanced Biliary Tract Cancers Previously Treated by Systemic Chemotherapy. 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 hope and health 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.
For more information, please visit: https://www.j-pharma.com/en/

Inquiries:

J-Pharma Co., Ltd.
Planning Department
TEL : +81-3-6432-4270
https://www.j-pharma.com/en/contact/