

December 8, 2025

J-Pharma Co., Ltd.

Nanvuranlat Registered on the U.S. Database ClinicalTrials.gov
~In Advance of the Initiation of the Global Phase 3 Clinical Trial~

J-Pharma Co., Ltd. announces that information on the global Phase 3 clinical trial of *nanvuranlat*, an L-type amino acid transporter 1 (LAT1) inhibitor for advanced biliary tract cancer, has been registered and published on the U.S. clinical trial database, ClinicalTrials.gov*.

- ClinicalTrials.gov ID NCT07265674
- URL <https://clinicaltrials.gov/study/NCT07265674>

* ClinicalTrials.gov is a database maintained by the U.S. National Library of Medicine (NLM) and jointly supported by the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA). The database offers information on ongoing clinical trials and clinical research.

About Global Phase 3 Clinical Trial (Study Name: Beacon-BTC)



Models are for illustrative purposes only.

The journey forward with advanced biliary tract cancer begins with a bright beacon of research.

The name “Beacon-BTC” reflects 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 J-Pharma’s investigational product, *nanvuranlat*, in patients with BTC receiving second-line therapy, an area where treatment options remain extremely limited.

The primary endpoint of the study is overall survival (OS). Beacon-BTC consists of two parts:

- Part A: A total of 30 patients will be enrolled in each of the four groups—three *nanvuranlat* dosing regimens and a Physician’s Best Choice (PBC)* control group—to determine the optimal dose.
- Part B: The selected *nanvuranlat* regimen will then be compared with PBC in 180 patients per group.

** 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.*

(Reference)

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/>

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