August 12, 2026

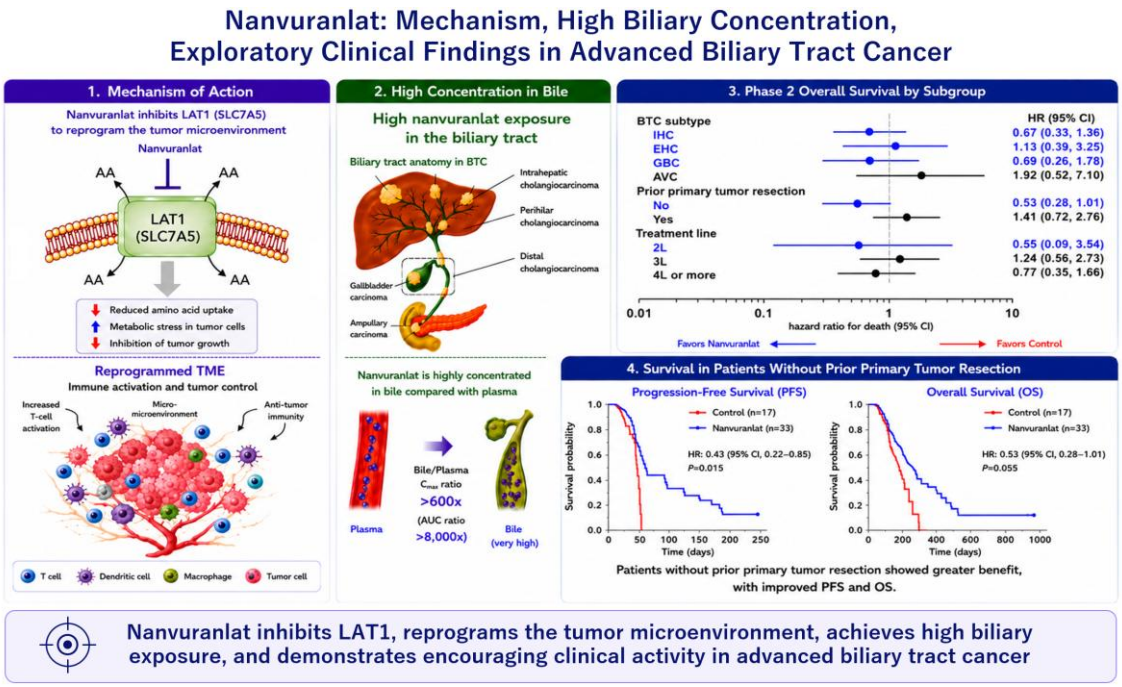
J-Pharma Co., Ltd.

Post Hoc Analysis of *Nanvuranlat* (JPH203)
in Advanced Biliary Tract Cancer Published in Cancers

— Exploratory Findings to Be Prospectively Evaluated in the Global Phase III Beacon-BTC Study —

J-Pharma Co., Ltd. (Head Office: Minato-ku, Tokyo; President and CEO: Masuhiro Yoshitake; hereinafter "J-Pharma" or the "Company") today announced that a paper reporting a post hoc analysis of data from Japanese Phase I and Phase II clinical trials of *nanvuranlat* (development code: JPH203) in patients with advanced biliary tract cancer has been published in the peer-reviewed scientific journal Cancers.

The paper reports exposure–response and subgroup analyses of clinical trial data accumulated to date and identifies scientific hypotheses warranting prospective evaluation in future clinical development. Although the analyses are exploratory and do not establish efficacy in any specific patient subgroup or define criteria for patient selection, the findings have informed scientific hypotheses that are being prospectively evaluated in the ongoing global Phase III Beacon-BTC study.



Relevance of the Paper to the Global Phase III Beacon-BTC Study

Beacon-BTC is a global Phase III clinical study in patients with unresectable advanced or recurrent biliary tract cancer whose disease has progressed following, or who are intolerant to, standard first-line therapy. Patients are randomized to one of multiple *nanvuranlat* dosing regimens or an investigator-selected treatment. The study evaluates efficacy, safety, tolerability, and pharmacokinetics, with overall survival (OS) as the primary endpoint.

By prospectively evaluating the scientific hypotheses identified in the paper through Beacon-BTC, J-Pharma aims to appropriately assess the therapeutic effect of *nanvuranlat* and generate the evidence required for regulatory submissions.

Comment from Masuhiro Yoshitake, President and CEO of J-Pharma Co., Ltd.

"The publication of these exploratory findings in a peer-reviewed journal is a significant milestone for the Company. This paper provides important scientific insights for evaluating the clinical value of *nanvuranlat*, and we will continue to rigorously evaluate its efficacy and safety through the ongoing global Phase III Beacon-BTC study."

"We also intend to leverage this publication to enhance scientific communication with researchers and healthcare professionals while supporting discussions with potential business partners. Our goal is to bring *nanvuranlat* to patients as a new treatment option as soon as possible."

Publication Details

Journal: Cancers

Title: Clinical and LAT1 Biomarker Correlates of Clinical Benefit from Nanvuranlat (JPH203) in Advanced Biliary Tract Cancer: A Post Hoc Analysis

Authors: Eric K. Rowinsky, Ghassan K. Abou-Alfa, Junji Furuse, Makoto Ueno, Masafumi Ikeda, Hiroko Tabuchi, Kazuo Sekiguchi, Michael Szarek

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Article URL: https://www.mdpi.com/2072-6694/18/15/2492

About *Nanvuranlat*

Nanvuranlat (development code: JPH203) 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. LAT1 (L-type amino acid transporter 1) is one of the transporters involved in cellular amino acid uptake and is known to be highly expressed in many cancer cells. 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 I clinical studies in multiple solid tumors and identified its potential for the treatment of advanced biliary tract cancer. A Phase II 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 Investigational New Drug (IND) application for clinical studies in cancer patients was accepted by the FDA. 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. Based on these developments, the Company initiated a global Phase III clinical trial in December 2025.

* 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. https://doi.org/10.1158/1078-0432.CCR-24-0461

Non-Clinical Combination Effects of *Nanvuranlat* (JPH203) and Immune Checkpoint Inhibitors (ICIs)

The combination effects of *nanvuranlat* and ICI antibodies were evaluated in a 4T1 syngeneic mouse xenograft model, which is resistant to cancer immunotherapy. The results showed that combination treatment with *nanvuranlat* and ICI antibodies significantly enhanced antitumor activity compared with each monotherapy.

The combination also increased CD4+ and CD8+ tumor-infiltrating lymphocytes (TILs) and reduced FoxP3-positive CD4+ T cells, which are involved in suppression of antitumor immunity [1, 2, 3].

In addition, an increase in the M1/M2 macrophage ratio and suppression of cancer-associated

fibroblast (CAF) accumulation were observed [3], suggesting that the combination of *nanvuranlat* and ICI antibodies may improve the tumor immune microenvironment.

1. Zhao Y et al. Targeting LAT1 with JPH203 to reduce TNBC proliferation and reshape suppressive immune microenvironment by blocking essential amino acid uptake. Amino Acids. 2025;57(1):27. https://doi.org/10.1007/s00726-025-03456-3
2. Huang R et al. Targeting glutamine metabolic reprogramming of SLC7A5 enhances the efficacy of anti-PD-1 in triple-negative breast cancer. Front Immunol. 2023;14:1251643. https://doi.org/10.3389/fimmu.2023.1251643
3. *Nanvuranlat* Investigator's Brochure Version 10.0, September 2025.

Related Information

- *Nanvuranlat* and biliary tract cancer
  https://www.j-pharma.com/en/pipeline/biliary_tract_cancer/
- Global Phase III trial (Beacon-BTC) for biliary tract cancer
  https://www.j-pharma.com/en/clinical_trial/biliary_tract_cancer_p3/
- Details of the investigator-initiated clinical trial evaluating the combination of nanburlat and an immune checkpoint inhibitor (jRCT)
  https://jrct.mhlw.go.jp/latest-detail/jRCT2031260086
- *Nanvuranlat* mechanism of action video
  https://www.j-pharma.com/assets/video/251209_EN.mp4

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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