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Securities Code: 520A Tokyo Stock Exchange Growth Market

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**J-Pharma Decides on Policy to Expand Part A of the Global Phase III Beacon-BTC Study of
Nanvuranlat to Japan and South Korea**

— Leveraging AMED Support to Reduce Financial Burden While Aiming to Generate Clinical Data
and Build a Foundation for Future Development —

J-Pharma Co., Ltd. (Head Office: Minato-ku, Tokyo; President and CEO: Masuhiro Yoshitake; hereinafter “J-Pharma” or the “Company”) announces that, following its selection for a support program of the Japan Agency for Medical Research and Development (AMED), its Board of Directors, at a meeting held on October 14, 2026, approved a policy to add Japan and South Korea as participating countries in Part A of the global Phase III Beacon-BTC study (the “Trial”) of *nanvuranlat* (development code: JPH203), a LAT1 inhibitor currently under development.

The specific implementation plans in Japan and South Korea will be developed taking into account consultations with the regulatory authorities in each country and the necessary regulatory procedures.

J-Pharma is currently conducting Part A in the United States, where study site activation and patient enrollment are underway. The Trial has been selected for AMED’s Global Research and Development Support Project for the Treatment of Intractable/Rare Diseases (GRiT) (the “AMED Support”), making it eligible for grant funding of up to JPY 1.5 billion. The actual amount will be determined after the formal grant decision and other required procedures.

J-Pharma will use the AMED Support to prepare for conducting Part A in Japan and South Korea, in addition to the United States. Through these preparations, J-Pharma aims to collect clinical data that reflect differences in patient characteristics across countries and regions, and establish a framework to support Part B and subsequent development. These efforts will support the continued global development of *nanvuranlat*.

■ **Overview of Beacon-BTC**

The global Phase III Beacon-BTC trial consists of two parts: Part A, which aims to select the optimal

dosing regimen for *nanvuranlat*, and Part B, which will evaluate the efficacy and safety of the selected regimen. Part A will involve approximately 120 patients and will assess efficacy, safety, pharmacokinetics, and other relevant factors to select the dosing regimen for Part B based on the results.

J-Pharma is currently conducting Part A in the United States, and the planned clinical trial sites are being activated on schedule. Following this decision, J-Pharma will proceed with preparations to conduct Part A in Japan and South Korea, including consultations with regulatory authorities and the necessary regulatory procedures.

■ Purpose and Expected Significance of Expansion into Japan and South Korea with AMED Support

The policy to expand into Japan and South Korea aims to advance the global development of *nanvuranlat* through the accumulation of clinical data and the establishment of an implementation framework with Part B and subsequent development in mind.

1. Accumulating Clinical Data Reflecting Differences in Patient Characteristics Across Countries and Regions

J-Pharma will proceed with preparations for conducting Part A in Japan and South Korea and, if conduct of the study becomes feasible in each country, aims to accumulate clinical data that reflect differences in patient characteristics across countries and regions.

2. Building a Foundation for Part B and Subsequent Development

To prepare for Part A in Japan and South Korea, J-Pharma will consult with regulatory authorities, proceed with the necessary regulatory procedures, hold discussions with candidate medical institutions, and establish the trial operational framework. J-Pharma aims to apply the experience gained from these preparations and the conduct of Part A to Part B and subsequent development. Specific plans for conducting Part B in each country will be considered based on the results of Part A and consultations with regulatory authorities.

3. Strengthening ties with trial sites and specialists in Japan and South Korea

J-Pharma will strengthen its collaboration with candidate medical institutions and specialists in biliary tract cancer in Japan and South Korea, and incorporate their knowledge of clinical practice and trial operations in each country into its development work.

It aims to use these collaborations and insights as it plans future global development.

4. Reducing development costs through AMED support

Following the formal grant award decision, J-Pharma plans to use the AMED Support to cover eligible expenses for Part A, in accordance with the terms of the grant award and the applicable grant conditions.

The AMED Support is expected to reduce the amount of development costs that J-Pharma must fund from its own resources. J-Pharma also considers this support valuable because receiving the grant does not involve issuing new shares, allowing J-Pharma to supplement its development funding without diluting existing shareholders' ownership interests.

■ Current Status of Preparations and Future Plans in Japan and South Korea

As part of its assessment of the feasibility of conducting Part A in Japan and South Korea, J-Pharma has been holding discussions with candidate medical institutions and has met with prospective investigators in both countries. These meetings were conducted as part of a preliminary assessment to understand clinical practice in each country and potential issues related to study conduct.

Following the Board of Directors' decision, J-Pharma will proceed with preparations toward expansion into Japan and South Korea. Whether the study will be conducted in each country, the timing of implementation, and the specific study plans will be determined based on the outcome of consultations with regulatory authorities and the necessary regulatory procedures.



Meeting with prospective investigators in South Korea regarding the feasibility of conducting Part A of Beacon-BTC
(October 12, 2026)

■ Future Outlook

J-Pharma is currently preparing its grant application. The potential impact of its selection for AMED Support and the policy to expand into Japan and South Korea on its development budget and financial forecasts is currently under review. J-Pharma will promptly disclose any matters requiring disclosure as they arise.

Related Information

- Global Phase III trial (Beacon-BTC) for biliary tract cancer

https://www.j-pharma.com/en/clinical_trial/biliary_tract_cancer_p3/

- J-Pharma Holds Investigator Meeting to Prepare for Expansion of the Global Phase III Beacon-BTC Study of Nanvuranlat to Japan (October 9, 2026)

<https://www.j-pharma.com/en/news/3755/>

- J-Pharma Selected for Funding under AMED's Global Research and Development Support Project for the Treatment of Intractable/Rare Diseases (October 5, 2026)

<https://www.j-pharma.com/en/news/3718/>

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. In 2018, J-Pharma began a Phase II clinical trial in patients with advanced biliary tract cancer, which demonstrated a statistically significant improvement in progression-free survival (PFS) compared with placebo, along with a favorable safety profile.*

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, on May 13, 2025, J-Pharma received a positive written response from the U.S. Food and Drug Administration (FDA) regarding compliance with quality standards for commercial-scale manufacturing in relation to chemistry, manufacturing and controls (CMC). 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>

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. Guided by this mission, J-Pharma focuses on LAT1 (L-type amino acid transporter 1), an SLC transporter discovered by its founder, and advances the development of new drugs to address the needs of patients with cancer and autoimmune diseases that are not adequately met by existing treatments.

For more information, please visit:

<https://www.j-pharma.com/en/>

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