October 1, 2024
J-Pharma Co., Ltd.

IND Application to Initiate Clinical Trials of NANVURANLAT for Cancer Patients Approved by U.S. FDA

We are pleased to announce that the U.S. Food and Drug Administration (FDA) approved our Investigational New Drug (IND) application for a clinical trial of nanvuranlat in cancer patients on September 25, 2024. We are currently continuing discussions with the FDA to conduct a Phase 3 trial in the U.S. in 2025.

The approval of the IND application is a major step forward in the development program of nanvuranlat for cancer patients in the United States. We are committed to the U.S. approval of nanvuranlat and to be a successful example of a Japanese drug discovery venture, and will do our utmost to develop an innovative drug that will meet the hopes of patients around the world.

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Nanvuranlat is a novel small molecule compound that selectively inhibits LAT1, discovered independently by our company. We conducted Phase I clinical trial for multiple solid tumors from 2015, and discovered its potential for biliary tract cancer. We then conducted a domestic Phase II trial for advanced biliary tract cancer over a period of three and a half years from 2018, and found that it showed useful clinical effects as a single agent.
Nanvuranlat is the first LAT1-targeted compound undergoing clinical studies and will become the first-in-class medicine when approved by competent authorities. The U.S. Food and Drug Administration (FDA) granted orphan drug designation to nanvuranlat in April 2022. With this designation, J-Pharma will receive benefits, including tax credits for qualified clinical trials, waiver of new drug application (NDA) application fee, and eligibility for market exclusivity for seven years post approval in the United States.