



**Jadeite Medicines Completes Phase 3 Trial of Odevixibat in
Progressive Familial Intrahepatic Cholestasis (PFIC) and Preparation of Dossier for
New Drug Application (NDA) in Japan**

TOKYO, JAPAN, 23th December 2024 - Jadeite Medicines Inc., (Jadeite Medicines) a clinical stage biopharmaceutical company headquartered in Tokyo, Japan (President & CEO, Eiichi Takahashi) has been conducting clinical studies of odevixibat in patients with PFIC in Japan under its strategic collaboration with Albireo Pharma Inc., a wholly-owned subsidiary of Ipsen (Euronext: IPN; ADR: IPSEY).

Jadeite Medicines completed the phase 3 trial (A4250-J005) and prepared the dossier required for the NDA for PFIC in Japan.

The NDA for this indication, based on the strategic collaboration, has been transferred to IPSEN Co., Ltd. headquartered in Tokyo, Japan (President & Representative Director: Kurt Rimkus), a wholly-owned subsidiary of Ipsen which is responsible for commercialization of the product.

Odevixibat is already approved for cholestatic pruritus in patients with Alagille syndrome (ALGS) and patients with PFIC in the United States and European countries and is marketed by Ipsen.

Through the development of odevixibat, Jadeite Medicines aspires to contribute to the treatment of patients suffering from PFIC. Jadeite Medicines commits to the health and quality of life for patients through our relentless R&D in drug development in order to fulfill patient unmet needs.

▽Progressive Familial Intrahepatic Cholestasis (PFIC)

PFIC is a spectrum of autosomal recessive genetic disorders in which cholestasis may lead to end-stage liver disease. PFIC is designated as an intractable disease (designation number 338) by the MHLW in Japan.

PFIC is estimated to affect between one in every 50,000 to 100,000 children born worldwide. PFIC represents 10% to 15% of cases of cholestasis in children. In Japan, estimated 100 patients suffer from PFIC.

Symptoms develop early with median age at onset of symptoms of approximately 3 months and jaundice, pale stools, and intractable pruritus become apparent at 3-4 months of age, accompanied by hepatosplenomegaly and growth failure. Currently there are no treatments except for symptomatic treatments in Japan and without conservative treatment patients will require surgical options including liver transplantation.

▽Odevixibat

Odevixibat is a once-daily, potent non-systemic ileal bile acid transport inhibitor (IBATi) that acts locally within the small intestine.

Odevixibat is approved and marketed by Ipsen in the United States, Europe and other territories for the treatment of cholestatic pruritus in patients with ALGS and patients with PFIC.

Odevixibat has also received orphan drug designation for the treatment of biliary atresia and primary biliary cirrhosis in the U.S. and Europe, and the Phase III BOLD trial in patients with biliary atresia is ongoing overseas.

▽Jadeite Medicines Inc.

Jadeite Medicines Inc. is a biopharmaceutical company established in 2020 to fulfill the unmet medical needs of patients in Japan by introducing and developing innovative medicines from around the world. Jadeite Medicines team consists of highly experienced professionals in the field of clinical development, regulatory, CMC and business development. Jadeite Medicines continues to search for first-in-class and best-in-class medicines from around the world to create a truly innovative product portfolio. Jadeite Medicines is backed by CBC Group, Asia's largest healthcare-dedicated investment firm. For more information, visit www.jadeitemedicines.co.jp.

▽Ipsen

Ipsen is a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience.

Ipsen's pipeline is fueled by external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Ipsen's teams in more

than 40 countries and partnerships around the world enable Ipsen to bring medicines to patients in more than 80 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipсен.com.