Jadeite Medicines to initiate Phase 3 Trial of Odevixibat in Alagille Syndrome in Japan

TOKYO, JAPAN, 5th April 2024 - Jadeite Medicines Inc., (Jadeite Medicines) a clinical stage biopharmaceutical company headquartered in Tokyo, Japan (President & CEO, Eiichi Takahashi) has announced initiation of a phase 3 trial in Alagille Syndrome (ALGS) for patients in Japan. This Phase 3 trial will evaluate the efficacy and safety of an oral dosage of odevixibat in Japanese ALGS patients. Odevixibat is marketed by Ipsen Pharma (Ipsen) in the United States for cholestatic pruritis in patients (≥12 months of age) with ALGS as well as for the treatment of pruritus in all subtypes of PFIC and in Europe for the treatment of all subtypes of PFIC.

Through the development of odevixibat, Jadeite Medicines aspires to contribute to the treatment of patients suffering from ALGS. 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.

▽Alagille Syndrome (ALGS)

ALGS is an inherited rare, genetic disorder that can affect multiple organ systems in the body including the liver, heart, skeleton, eyes and kidneys. Liver damage may result from having fewer than normal, narrowed or malformed bile ducts, which leads to toxic bile acid build-up, which in turn can cause scarring and progressive liver disease. Approximately 95% of patients with the condition present with chronic cholestasis, usually within the first three months of life and as many as 88% also present with severe, intractable pruritus. The estimated global incidence of ALGS is 3 in 100,000 live births. In Japan, an estimated 200~300 patients suffer from ALGS. ALGS is designated as an intractable disease (designation number 297) by the MHLW.

▽Odevixibat

Odevixibat is a once-daily, potent non-systemic ileal bile acid transport inhibitor (IBATi) that acts locally within the small intestine. Odevixibat is the first ever approved treatment for all subtypes of PFIC for patients above the age of three months in the U.S. (for the treatment of pruritis). Odevixibat is also approved by the EMA and the Medicines and Healthcare Products Regulatory Agency of the United Kingdom for all subtypes of PFIC for patients above the age of six months and is being widely commercialized in Europe. Odevixibat has been granted orphan drug designation in the U.S. and Europe. Odevixibat is also commercialized for ALGS in the U.S. for patients living with cholestatic pruritis due to ALGS. Ipsen is also studying the use of odevixibat in other rare pediatric cholestatic liver diseases with the BOLD Phase 3 clinical trial in patients with biliary atresia.

▽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.