News release

Kyowa Kirin Announces Initiation of Phase 3 AOBA Study of KK8398 (Infigratinib) in Patients with Achondroplasia in Japan

Tokyo, Japan, November 21, 2025 -- Kyowa Kirin Co., Ltd. (TSE:4151, President and COO: Abdul Mullick, "Kyowa Kirin") today announced that the first patient has been dosed on November 20 in the AOBA study (jRCT2031240562), initiating the Phase 3 clinical study in Japan of KK8398 (infigratinib), an investigational FGFR1–3 oral inhibitor, for patients with achondroplasia. The AOBA study is a multicenter, open-label, single-arm Phase 3 study being conducted domestically.

"Delivering Life-changing value in the bone and mineral domain, one of Kyowa Kirin's focus disease areas, is our mission," said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. "We are pleased to announce the initiation of the AOBA Phase 3 clinical study of KK8398 (infigratinib) for achondroplasia. Achondroplasia, a designated intractable disease in Japan, involves not only short stature but also a variety of physical and social challenges that impact patients throughout their lifetime. Through this study, we aim to establish scientific evidence of the safety and efficacy of KK8398 and work to provide new treatment options that improve the quality of life for patients in Japan as soon as possible."

This Phase 3 study in Japan will evaluate the efficacy and safety of KK8398 in approximately six patients aged 3 to under 18 years, with a 52-week treatment and observation period. The primary endpoint is annualized height growth velocity; secondary endpoints include growth and body proportion parameters, quality of life (QOL), and safety measures. The study seeks to provide a new treatment option in Japan while aligning with data from global studies.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About KK8398 (Infigratinib)

KK8398 (infigratinib) is a selective, oral small-molecule inhibitor of FGFR1–3. BridgeBio Pharma is currently conducting a global Phase 3 study for achondroplasia.. In Japan, Kyowa Kirin holds exclusive licensing rights for the development and commercialization of KK8398 in skeletal dysplasias.

About Achondroplasia

Achondroplasia, a representative genetic condition characterized by short stature, occurs in approximately 1 in 20,000 live births and affects about 55,000 individuals in the US and EU and approximately 6,000 in Japan. It is associated with a range of health and quality-of-life challenges, including short stature, foramen magnum stenosis, ventricular enlargement, spinal canal stenosis, kyphosis, obstructive sleep apnea, respiratory issues, otitis media, hearing loss, dental irregularities, limb complications, and obesity. Over 97% of cases have activating mutations in FGFR3, and the activating mutations are currently the only known genetic mutations that cause achondroplasia.

About Kyowa Kirin

Kyowa Kirin aims to discover novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, we have invested in drug discovery and biotechnology innovation for more than 70 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients affected by a severe or rare disease. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our four regions – Japan, Asia Pacific, North America, and EMEA/International. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com/

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (BridgeBio) is a new type of biopharmaceutical company founded to discover, create, test, and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information, visit **bridgebio.com** and follow us on **LinkedIn**, **X**, **Facebook**, **Instagram**, and **YouTube**.