

# News release

## **Kyowa Kirin Highlights Positive Phase 3 Topline Data from BridgeBio's Global PROPEL 3 Study of Infigratinib in Achondroplasia**

**Tokyo, Japan, February 16, 2026** -- Kyowa Kirin Co., Ltd. (TSE:4151, President and COO: Abdul Mullick, "Kyowa Kirin") today announced that its development partner BridgeBio Pharma, Inc. (hereinafter "BridgeBio") reported topline data from PROPEL 3, a global Phase 3 clinical study of infigratinib, an oral FGFR1-3 inhibitor under development as KK8398, in people with achondroplasia. PROPEL 3 is a pivotal, one-year, 2:1 randomized, placebo-controlled study conducted globally (excluding Japan) evaluating the efficacy and safety of infigratinib in children with achondroplasia aged 3 to less than 18 years with open growth plates.

**BridgeBio's news release with disclosed results can be found [here](#), and investor webinar recording and presentation can be found [here](#).**

The topline data demonstrated that the primary endpoint was achieved, revealing high efficacy and favorable tolerability. Furthermore, the results demonstrated the potential of infigratinib as a new and oral option for achondroplasia. Additional results will be shared in future medical conferences. In response to these results, BridgeBio plans to meet with regulatory authorities to discuss submission for regulatory approval in the U.S. and EU in the second half of 2026.

In February 2024, Kyowa Kirin obtained an exclusive license from BridgeBio for the development and commercialization of infigratinib for skeletal dysplasia in Japan. In November 2025, Kyowa Kirin initiated the AOBA study (jRCT2031240562), a phase 3 clinical trial of KK8398 (infigratinib) in Japanese people with achondroplasia. This study aims to evaluate the efficacy and safety in Japanese people with achondroplasia and establish a new and oral option in Japan. Building upon the accumulated global knowledge, we plan to continue generating clinical data tailored to the Japanese healthcare environment.

Kyowa Kirin has positioned the bone and mineral field as one of its focus disease areas and has continuously addressed unmet medical needs including rare diseases. In achondroplasia, we aim to provide options based on scientific evidence while listening carefully to the voices of individuals, their families, and healthcare professionals. Moving forward, we will continue to value the insights gained through clinical trials and remain committed to steadily and sincerely creating value that contributes to real-world clinical practice.

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/>