News release

Kyowa Kirin Highlights FDA Acceptance and Priority Review of BridgeBio's NDA for Oral Infigratinib for Children Living with Achondroplasia

- FDA Acceptance and Priority Review Represent an Important Regulatory Milestone for the Development of a Potential New Oral Treatment Option for Children Living with Achondroplasia -

Tokyo, Japan, October 7, 2026 -- Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Abdul Mullick, "Kyowa Kirin") today announced that its development partner, BridgeBio Pharma, Inc. (“BridgeBio”), which is responsible for the development and commercialization of infigratinib in the United States, has received acceptance from the U.S. Food and Drug Administration (“FDA”) for its New Drug Application (“NDA”) for oral infigratinib for the treatment of children with achondroplasia. The FDA has granted Priority Review to the application and assigned a target action date of February 4, 2027.

The FDA’s acceptance of BridgeBio’s NDA represents an important advancement in the company’s U.S. regulatory program. In addition, the granting of Priority Review, a designation reserved for medicines that, if approved, may offer significant improvements in the treatment of serious conditions, marks an important milestone in the development of oral infigratinib and a significant step toward potentially expanding treatment options for children living with achondroplasia. Kyowa Kirin holds an exclusive license for the development and commercialization of infigratinib for skeletal dysplasias in Japan, where the investigational medicine is being developed as KK8398. As the company continues to advance KK8398 in Japan, including through the ongoing Phase 3 AOBA study, Kyowa Kirin views this U.S. regulatory progress as an important milestone that further supports the potential of the program and reinforces its commitment to bringing a potential new treatment option to patients and families in Japan. BridgeBio also intends to submit a Marketing Authorization Application (MAA) for achondroplasia to the European Medicines Agency (EMA) in the fourth quarter of 2026, representing the next anticipated step in the program's global regulatory development.

BridgeBio’s NDA is supported by results from PROPEL 3, a global pivotal Phase 3 clinical study evaluating oral infigratinib in children with achondroplasia. PROPEL 3 met its primary endpoint of change from baseline in annualized height velocity at Week 52, demonstrating a statistically significant improvement with oral infigratinib compared with placebo. Statistically significant improvements were also observed in measures of body proportionality and arm span. Exploratory analyses showed favorable trends compared with placebo in measures related to sleep apnea and middle ear events. As these were exploratory findings, further evaluation is needed to understand their clinical significance. Oral infigratinib was generally well tolerated in the PROPEL 3 study. No study-drug-related serious adverse events were reported, and no participants discontinued treatment because of study-drug-related adverse events. The results of the study were published as an original research article in The *New England Journal of Medicine (NEJM)* and were also presented at the International Congress of Children’s Bone Health 2026.

“The FDA’s acceptance of BridgeBio’s NDA and the granting of Priority Review represent an important step toward potentially bringing a new treatment option to children living with achondroplasia and their families,” said Yoshifumi Torii, Ph.D., Chief Medical Officer of Kyowa Kirin. “Achondroplasia is associated with a range of lifelong medical and physical challenges, and the needs and priorities of individuals and families are diverse.

The results generated to date suggest that oral infigratinib may have the potential to address aspects of the condition beyond growth alone. While the FDA's review remains ongoing, we are encouraged by this milestone. In collaboration with BridgeBio, Kyowa Kirin remains committed to advancing the development of KK8398 in Japan, including through the ongoing Phase 3 AOBA study, with scientific rigor and a strong sense of urgency. Our goal is to bring a potential new treatment option to patients and families in Japan."

In February 2024, Kyowa Kirin obtained an exclusive license from BridgeBio for the development and commercialization of infigratinib for skeletal dysplasias in Japan. In November 2025, Kyowa Kirin initiated the AOBA study (jRCT2031240562), a Phase 3 clinical trial of KK8398 (infigratinib) in Japanese patients with achondroplasia. This study is designed to evaluate the efficacy and safety of KK8398 in Japanese patients and to generate clinical evidence relevant to patients and clinical practice in Japan.

Kyowa Kirin has positioned the bone and mineral field as one of its focus disease areas and has continuously worked to address unmet medical needs, including those associated with rare diseases. The company will continue to advance the development of KK8398 in collaboration with BridgeBio, with the aim of delivering a new oral treatment option for people living with achondroplasia in Japan.

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

About KK8398 (Infigratinib)
KK8398 (infigratinib) is an investigational, selective, oral small-molecule inhibitor of FGFR1–3. BridgeBio conducted the global pivotal Phase 3 PROPEL 3 study of oral infigratinib in children with achondroplasia. In Japan, Kyowa Kirin holds an exclusive license for the development and commercialization of infigratinib for skeletal dysplasias. Infigratinib is investigational and has not been approved for the treatment of achondroplasia in Japan.

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/