KYOWA KIRIN

News release

Kyowa Kirin Highlights Publication in the *New England Journal of Medicine* of BridgeBio's Phase 3 PROPEL 3 Trial of Oral Infigratinib in Children Living with Achondroplasia

Tokyo, Japan, July 2, 2026 -- Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Abdul Mullick, "Kyowa Kirin") today announced that its development partner BridgeBio Pharma, Inc. (hereinafter "BridgeBio") has published positive results from the global Phase 3 PROPEL 3 study of infigratinib in children with achondroplasia in The *New England Journal of Medicine (NEJM)*.

Publication of the Phase 3 data in *NEJM*, a leading peer-reviewed medical journal, reflects that the results have undergone rigorous peer review. Notably, this represents the first and only Phase 3 data from an achondroplasia clinical study to be published in *NEJM*. *NEJM* is a widely read, peer-reviewed medical journal with significant global influence, and publications in the journal are broadly recognized as important contributions to clinical medicine.

BridgeBio reported that positive results from PROPEL 3, a global pivotal Phase 3 study evaluating oral infigratinib, were published as an original research article in *NEJM* and simultaneously presented at the International Congress of Children's Bone Health (ICCBH) 2026. PROPEL 3 is a pivotal, global, placebo-controlled Phase 3 study evaluating the efficacy and safety of infigratinib in children with achondroplasia.

The positive results shared in *NEJM* from PROPEL 3 include (As reported by BridgeBio)

- PROPEL 3 successfully met the primary endpoint of change from baseline in annualized height velocity, with a LS mean treatment difference against placebo of +1.74 cm/yr ($p<0.0001$). The observed mean difference was +2.10 cm/yr ($p<0.0001$). Both values are the largest observed in a Phase 3 clinical study in achondroplasia
- PROPEL 3 successfully met the key secondary endpoint of change from baseline in height Z-score (achondroplasia reference population) at Week 52 ($p<0.0001$), with an LS mean increase on the treatment arm of +0.41 SD
- In a pre-specified exploratory analysis of the key secondary endpoint, oral infigratinib achieved the first statistically significant improvement in body proportionality against placebo in achondroplasia, demonstrating an LS mean treatment difference of -0.05 ($p<0.05$) against placebo in children younger than 8 years old (>50% of the participants)
- Infigratinib was well-tolerated, with:
  - No discontinuations related to study drug
  - No serious adverse events related to study drug
  - 3 cases (4%) of hyperphosphatemia, all mild, transient, asymptomatic, and not requiring dose reductions or discontinuations
  - No adverse events associated with inhibition of FGFR1 or FGFR2 (e.g., retinal or corneal)

- Additional data presented at ICCBH showed infigratinib improved arm span Z-score vs. placebo by +0.37 SD ($p<0.0001$), marking the first statistically significant improvement in arm span from a placebo-controlled achondroplasia trial at 52 weeks.

These findings may contribute to the clinical evaluation of the PROPEL 3 study and provide important information for assessing the potential of infigratinib as an investigational treatment option for achondroplasia. BridgeBio has indicated its intention to submit a New Drug Application (NDA) in the United States in the third quarter of 2026 with launch anticipated in early to mid 2027, and a Marketing Authorization Application (MAA) in Europe 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 patients with achondroplasia. This study aims to evaluate efficacy and safety in Japanese patients and to aim to provide a new oral treatment option in Japan, building upon global clinical data.

Kyowa Kirin is committed to addressing unmet medical needs in rare conditions, including skeletal dysplasias, and will continue to advance the development of infigratinib with the aim of delivering a new 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 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/