



NEWS RELEASE

bridgebio pharma and kyowa kirin announce partnership with an upfront payment of \$100 million for an exclusive license on infigratinib in skeletal dysplasias in japan

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- BridgeBio grants Kyowa Kirin exclusive license to develop and commercialize infigratinib for skeletal dysplasias in Japan
- BridgeBio to receive upfront payment of USD 100 million with royalties up to the high-twenties percent, with additional milestone-based payments
- Infigratinib is a once daily oral treatment option under development for achondroplasia, which was well-tolerated and demonstrated potentially best-in-class efficacy in PROPEL 2, a Phase 2 study in children with achondroplasia
- PROPEL 3, a Phase 3 study of infigratinib in achondroplasia is underway globally outside of Japan with the first child dosed in December 2023
- Infigratinib adds to Kyowa Kirin's successful portfolio in the therapeutic areas of bone & mineral diseases

PALO ALTO, Calif. and TOKYO, Feb. 07, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio) and Kyowa Kirin Co., Ltd (TSE:4151) (Kyowa Kirin) today announced a partnership wherein BridgeBio's affiliate, QED Therapeutics, grants Kyowa Kirin an exclusive license to develop and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan. In exchange, BridgeBio will receive an

upfront payment of USD 100 million as well as royalties up to the high-twenties percent on sales of infigratinib in Japan, with the potential for additional milestone-based payments. Infigratinib is an oral small molecule designed to inhibit FGFR3 and thus target FGFR3-driven skeletal dysplasias at their source, including achondroplasia and hypochondroplasia.

“We are pleased to partner with Kyowa Kirin given their community-oriented core mission to bring smiles to faces by providing innovative medicines with life-changing value, which has seen success with their commercialization of Crysvida and other rare disease drugs. The BridgeBio vision is to help bring people access to novel treatments and trials, and so we are pleased that this collaboration will ensure the development of infigratinib for children living with achondroplasia, and eventually for other skeletal dysplasias in Japan,” said Neil Kumar, Ph.D., BridgeBio’s CEO and founder.

“By partnering with Kyowa Kirin, we hope to significantly accelerate the development of infigratinib to potentially provide options for children with achondroplasia, hypochondroplasia, and eventually skeletal dysplasias in Japan. We hear the need from the community for a once-daily oral treatment option and are looking forward to initiating our trials in Japan at a later date,” said Justin To, CEO of QED Therapeutics, BridgeBio’s affiliate for skeletal dysplasias.

“We are thrilled to announce that we have signed the License Agreement with BridgeBio,” said Yasuo Fujii, MBA., Chief Strategy Officer, Managing Executive Officer, Vice President, Head of Strategy Division at Kyowa Kirin. “It is important for us to strengthen our portfolio by introducing pipelines in the fields of bone & mineral disorders, including achondroplasia. Based on the results from the latest clinical trials, we believe BridgeBio’s infigratinib has high potential for treating achondroplasia. We will steadily advance the development in Japan and aim to deliver life-changing value to people with skeletal dysplasias including achondroplasia.”

In December 2023, BridgeBio dosed the first child in PROPEL 3, a one-year, 2:1 randomized, placebo-controlled Phase 3 pivotal trial, evaluating the efficacy and safety of infigratinib in children with achondroplasia aged 3 to <18 years with open growth plates. The Phase 3 builds on the success of PROPEL 2, a Phase 2 trial of infigratinib in achondroplasia which demonstrated a +3.38cm/yr increase in annualized height velocity, the strongest clinical result published to date. In Japan, Kyowa Kirin will start to discuss with Pharmaceuticals and Medical Devices Agency (PMDA) of Japan in 2024, with the aim of initiating a Japanese registrational trial in 2025.

“As the father of a child with achondroplasia, I am keenly aware of the health and mental health issues of people affected by the physical characteristics of living with achondroplasia. GLORY TO ACHONDROPLASIA is deeply grateful for the time spent by researchers and practitioners who support progress in medicine and society, as well as by people affected by the condition and their families. When considering the future of children with achondroplasia, we as a support organization believe it is our absolute responsibility to improve treatment options

and social recognition. We are pleased for BridgeBio to partner with Kyowa Kirin and look forward to collaborating on our future responsibilities,” said Eihaku Itooka, founder and president of GLORY TO ACHONDROPLASIA, a Japanese bone dysplasia patient advocacy organization.

Information about PROPEL 3 (NCT06164951) can be found **here** on clinicaltrials.gov. Additionally, BridgeBio expects to initiate ACCEL, an observational lead-in study for infigratinib in hypochondroplasia, a skeletal dysplasia closely related to achondroplasia and similarly driven by FGFR3 gain-of-function variants, in the first half of 2024. BridgeBio has previously presented promising preclinical data for hypochondroplasia at ENDO 2023 and ASHG 2022.

About Achondroplasia

Achondroplasia is the most common cause of disproportionate short stature, affecting approximately 55,000 people in the U.S. and EU, and 6,000 in Japan. Achondroplasia impacts overall health and quality of life, leading to medical complications such as obstructive sleep apnea, middle ear dysfunction, kyphosis, and spinal stenosis. The condition is uniformly caused by an activating mutation in FGFR3.

About BridgeBio Pharma, Inc.

BridgeBio Pharma (BridgeBio) is a commercial-stage biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. 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** and **Twitter**.

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>.

BridgeBio Pharma, Inc. Forward-looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are usually identified by the use of words such as “anticipates,” “believes,” “estimates,”



“expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements, including statements relating to expectations, plans, and prospects regarding the success of our exclusive license agreement with Kyowa Kirin to develop and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan; BridgeBio’s eligibility to receive an upfront payment, future royalty payments, and potentially additional milestone-based payments under the license agreement; the clinical, therapeutic and market potential of our clinical development program for infigratinib in achondroplasia; the progress of the clinical trials of infigratinib in achondroplasia and hypochondroplasia, including the continuation of PROPEL 3, our Phase 3 pivotal trial evaluating the efficacy and safety of infigratinib in children with achondroplasia aged 3 to <18 years with open growth plates, the expectation of Kyowa Kirin’s starting discussions with PMDA of Japan in 2024, with the aim of initiating a Japanese Phase 3 trial in 2025, and the expectation of our initiation of ACCEL, an observational lead-in study for infigratinib in hypochondroplasia, in the first half of 2024; the statements regarding the expectations for the partnership between BridgeBio and Kyowa Kirin and the potential benefits of infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan, including such statements in the quotes of Dr. Kumar, Mr. To, Mr. Fujii and Mr. Itooka, and the timing of these events, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, initial and ongoing data from our clinical trials not being indicative of final data, the design and success of ongoing and planned clinical trials, difficulties with enrollment in our clinical trials, adverse events that may be encountered in our clinical trials, the FDA or other regulatory agencies not agreeing with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the success of our license agreement with Kyowa Kirin, potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the impacts of current macroeconomic and geopolitical events, including changing conditions from the COVID-19 pandemic, hostilities in the Middle East and Ukraine, increasing rates of inflation and rising interest rates, on our overall business operations and expectations, as well as those risks set forth in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2022 and our other filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ

materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

BridgeBio Media Contact:

Vikram Bali

contact@bridgebio.com

(650)-789-8220