NEWS RELEASE

# bridgebio announces infigratinib is the first ever investigational therapeutic option for achondroplasia to be awarded breakthrough therapy designation by the fda

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- Breakthrough Therapy Designation was granted based on preliminary clinical evidence from the PROPEL 2 clinical trial, meeting the FDA's requirement of potentially demonstrating substantial improvement in efficacy over available therapies on clinically significant endpoint(s)

- BridgeBio will leverage the benefits of Breakthrough Therapy Designation to expedite the development and regulatory review of infigratinib in the United States and if approved, infigratinib could be the first-in-class oral therapeutic option for children living with achondroplasia

- In Cohort 5 of PROPEL 2 (0.25 mg/kg/day), oral treatment with infigratinib resulted in a statistically significant and sustained increase in annualized height velocity (AHV), with a mean change from baseline of +2.51cm/yr at Month 12, and +2.50 cm/yr at Month 18 (p=0.0015) and statistically significant improvement in body proportionality at Month 18 (p-value of 0.001)

PALO ALTO, Calif., Sept. 17, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio), a commercial-stage biopharmaceutical company focused on genetic diseases, today announced that the FDA has granted Breakthrough Therapy Designation to oral infigratinib under development for children with achondroplasia.

Breakthrough Therapy Designation is designed to expedite the development and regulatory review of drugs in the U.S. that meet stringent criteria. Drugs qualifying for this Designation must show preliminary clinical evidence that the drug may demonstrate a substantial improvement on clinically significant endpoints over available therapies.

“The receipt of Breakthrough Therapy Designation, the first ever for a treatment being developed for children with achondroplasia, marks another important milestone for our skeletal dysplasia program. This recognition by the FDA further confirms the strength of our Phase 2 data, and the substantial improvement on clinically significant endpoints over available therapies. We are excited by what this means for the community, and we look forward to working closely with FDA to expedite the development of infigratinib and access for families to an oral option,” said Adora Ndu, Pharm.D., J.D., Chief Regulatory Affairs Officer of BridgeBio.

The Designation was received based on PROPEL 2 data, which showed that in Cohort 5, infigratinib resulted in a statistically significant and sustained increase in AHV, with a mean change from baseline of +2.51cm/yr at Month 12, and +2.50 cm/yr at Month 18 (p=0.0015). There was also statistically significant improvement in body proportionality at Month 18 (p-value of 0.001).

“From the outside perspective, achondroplasia may appear to affect only the height of an individual. The reality is that achondroplasia is a skeletal dysplasia which could impact aspects of health-related quality of life and functionality. As a parent of a teenager with achondroplasia and an advocate for the community, I am pleased to learn that the FDA has granted infigratinib with its Breakthrough Therapy Designation,” said Munira Shamim, Founder of Growing Stronger, a U.S. advocacy group that supports research and develops resources for the care of individuals with achondroplasia. “This action represents a significant step towards offering the first oral treatment option more readily for families living with achondroplasia. Having a wider range of therapies empowers families with greater control and choice over their healthcare decisions. We are grateful to the medical, research, and regulatory communities for recognizing and addressing the needs of families with achondroplasia, allowing them to potentially lead lives with increased confidence and improved functionality.”

PROPEL 3, the global Phase 3 registrational study of infigratinib in achondroplasia, continues to enroll on schedule, with completion of enrollment anticipated by the end of the year. Information about PROPEL 3 (**NCT06164951**) can be found on clinicaltrials.gov. BridgeBio is committed to exploring the potential of infigratinib on wider medical and functional impacts of achondroplasia, hypochondroplasia and other skeletal dysplasias, which hold significant unmet needs for families.

In addition to receipt of Breakthrough Therapy Designation, infigratinib has also received Orphan Drug Designation, Fast Track Designation, and Rare Pediatric Disease Designation for achondroplasia from the FDA. If infigratinib is approved, BridgeBio may qualify for a Priority Review Voucher.

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (BridgeBio) is a commercial-stage biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who live with 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**, **Twitter** and **Facebook**.

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," "continues," "estimates," "expects," "hopes," "intends," "may," "plans," "projects," "remains," "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 the clinical, therapeutic and market potential of our programs and product candidates, including our clinical development program for infigratinib in achondroplasia, the timing and success of our clinical development programs, the progress of our ongoing and planned clinical trials of infigratinib in achondroplasia, hypochondroplasia and other skeletal dysplasias, infigratinib's potential for obtaining a Priority Review Voucher, our planned interactions with regulatory authorities, the statements regarding the potential clinical benefits of infigratinib for patients with achondroplasia in the quotes of Munira Shamim 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 ability of infigratinib to retain Breakthrough Therapy Designation, Fast Track Designation, Rare Pediatric Disease Designation, and Orphan Drug Designation from the U.S. Food and Drug Administration, and potential adverse impacts due to global health emergencies, including 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 hostilities in Ukraine and in Israel and the Gaza Strip, increasing rates of inflation and rising interest rates, on our business operations and expectations, as well as those risks set forth in the Risk Factors section of our most recent Annual Report on Form 10-K 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.

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