BRIDGEBIO

NEWS RELEASE

BridgeBio Announces FDA Acceptance and Priority Review of NDA for Oral Infigratinib for Children with Achondroplasia

10/6/2026

- Accepted for Priority Review with a PDUFA target action date of February 4, 2027; being granted Priority Review by the FDA underscores the significant unmet need for an oral targeted therapeutic option for children with achondroplasia

- If approved, oral infigratinib would be the first and only approved oral therapy and a potential best-in-class treatment option for children with achondroplasia

- PROPEL 3 met its primary endpoint and key secondary endpoints, delivering the strongest efficacy package reported to date in achondroplasia: the largest AHV treatment effect of any Phase 3 study (+2.10 cm/yr; $p<0.0001$), and the first and only statistically significant improvement in both body proportionality and arm span in an achondroplasia Phase 3 trial (Proportionality: mean difference of -0.05 in ages 3–8, $p<0.05$; arm span z-score: +0.37 SD, $p<0.0001$)

-Treatment with oral infigratinib for 52 weeks in PROPEL 3 also resulted in favorable trends against placebo in clinically meaningful exploratory endpoints including sleep apnea and otitis media events

- BridgeBio anticipates U.S. launch of oral infigratinib upon approval

PALO ALTO, Calif., Oct. 06, 2026 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a commercial-stage, multi-product biopharmaceutical company focused on developing medicines for genetic conditions, today announced the FDA has accepted for filing its New Drug Application (NDA) with Priority

Review for oral infigratinib for the treatment of children with achondroplasia. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of February 4, 2027, and BridgeBio is prepared to launch oral infigratinib upon approval.

"Being granted Priority Review means we are one step closer to potential FDA approval of the first oral treatment option for children with achondroplasia," said Justin To, Chief Executive Officer of BridgeBio Skeletal Dysplasias. "We also understand that for many families, it's about more than just height or having an oral option. To that end, we are excited by the data we have generated on arm span, sleep apnea, ear infections, and proportionality, and we remain committed to further evaluate and share the impact of oral infigratinib on measures beyond growth. We are grateful to the families and investigators who have partnered with us, and we are moving with urgency alongside the FDA."

PROPEL 3, the global Phase 3 pivotal study of oral infigratinib in children with achondroplasia, met its primary endpoint of change from baseline in annualized height velocity (AHV) at Week 52 (LS mean treatment difference of +1.74 cm/year; mean treatment difference of +2.10 cm/year; $p<0.0001$) and its key secondary endpoint of change from baseline in height Z-score ($p<0.0001$). In a pre-specified exploratory analysis in children younger than 8 years (more than half of participants), oral infigratinib became the first therapeutic option to show a statistically significant improvement in body proportionality against placebo in a randomized achondroplasia trial. Oral infigratinib was well tolerated, with no discontinuations or serious adverse events related to study drug. These data were published as an original research article in The New England Journal of Medicine and simultaneously presented at the International Congress of Children's Bone Health (ICCBH) 2026 in a late-breaking oral presentation. The results can be found **here**. Additionally, BridgeBio also shared emerging data for oral infigratinib at ESPE about improvements beyond height for people with achondroplasia, including stabilizing sleep apnea measures, reducing rate of ear infections, and impacting body composition. The results can be found **here**.

"For children and families living with achondroplasia, today's news represents meaningful progress toward potentially expanding the range of available options," said Michael Hughes, Chair of the Biotech Industry Liaison Committee at Little People of America. "Our community holds diverse priorities and perspectives, and what matters is that individuals and families have meaningful choices as they consider their own healthcare goals. This milestone brings us one step closer to potentially having another option for families to consider together with their healthcare providers. We appreciate BridgeBio's continued engagement with the achondroplasia community and its efforts to incorporate community perspectives throughout the development process."

BridgeBio intends to submit a Marketing Authorization Application (MAA) for achondroplasia to the European Medicines Agency (EMA) in the fourth quarter of 2026.

Oral infigratinib has received Breakthrough Therapy Designation from the FDA based on results from the PROPEL 2 clinical trial, which met the FDA's requirement of potentially demonstrating substantial improvement in efficacy over available therapies on clinically significant endpoints. Oral infigratinib is the only therapeutic option in development for achondroplasia to hold Breakthrough Therapy Designation. In addition, oral infigratinib has received Orphan Drug Designation, Fast Track Designation, and Rare Pediatric Disease Designation for achondroplasia from the FDA, as well as Orphan Drug Designation from the EMA.

Information about PROPEL I&T trial (NCT07169279) can be found **here** on **clinicaltrials.gov**. Information about ACCEL, the Company's observational lead-in study for oral infigratinib in hypochondroplasia's Phase 3 study (NCT06410976) can be found **here**, and information about ACCEL 2/3, BridgeBio's Phase 2/3 clinical study of oral infigratinib in hypochondroplasia (NCT06873035) can be found **here**. BridgeBio is committed to exploring the potential of oral infigratinib on wider medical and functional impacts of achondroplasia, hypochondroplasia, and other skeletal dysplasia conditions, which hold significant unmet needs for families.

About Achondroplasia

Achondroplasia is the most common cause of disproportionate short stature, affecting approximately 55,000 people in the U.S. and European Union (EU), including up to 10,000 children and adolescents with open growth plates. Achondroplasia can be associated with medical complications such as obstructive sleep apnea, middle ear dysfunction, kyphosis, and spinal stenosis, which may impact overall health and wellbeing. The condition is uniformly caused by an activating variant in FGFR3.

About Oral Infigratinib

Oral infigratinib is an investigational small molecule designed to inhibit FGFR3 signaling and target skeletal dysplasias, including achondroplasia and hypochondroplasia, at their source. Overactivating FGFR3 pathogenic variants drive downstream MAPK and STAT1 signaling that aberrates growth plate development, thereby causing disproportionate short stature and the potential for serious health complications. Oral infigratinib improves bone growth by decreasing the overactivity of FGFR3. Oral infigratinib has received Breakthrough Therapy Designation, Orphan Drug Designation, Fast Track Designation, and Rare Pediatric Disease Designation from the U.S. FDA, as well as Orphan Drug Designation from the European Medicines Agency (EMA).

About BridgeBio

BridgeBio exists to develop transformative medicines for genetic conditions. Millions of people worldwide living with genetic conditions lack treatment options, often because drug development for small patient populations can be commercially challenging. We aim to bridge the gap between advancements in genetic science and meaningful medicines for underserved patient populations. Our decentralized, hub-and-spoke model is designed for speed, precision, and scalability. Autonomous and empowered teams focus on individual conditions, while a central hub

provides the clinical, regulatory, and commercial capabilities needed to bring innovation to market. For more information, visit **bridgebio.com** and follow us on **LinkedIn**, **X**, **Facebook**, **Instagram**, **YouTube**, and **TikTok**.

BridgeBio Forward-Looking Statements

These forward-looking statements include statements regarding the potential clinical significance and therapeutic implications of the data regarding oral infigratinib, including the potential for oral infigratinib to provide benefits beyond growth and to meaningfully affect a broader range of medical and functional outcomes associated with achondroplasia; the potential for oral infigratinib to become the first and only approved oral therapy and a potential best-in-class option for children living with achondroplasia; the potential regulatory approval and commercialization of oral infigratinib, including the timing and likelihood of potential FDA approval and BridgeBio's anticipated U.S. launch upon approval; BridgeBio's plans to submit a Marketing Authorization Application for oral infigratinib in achondroplasia to the European Medicines Agency in the fourth quarter of 2026; BridgeBio's plans to further evaluate and share the potential impact of oral infigratinib on measures beyond growth; and BridgeBio's plans to continue exploring the potential of oral infigratinib to address broader medical and functional impacts of achondroplasia, hypochondroplasia and other skeletal dysplasia conditions.

Although the Company believes that its plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, the Company 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 the Company's clinical trials not being indicative of final data; the design, enrollment, conduct, timing and success of ongoing and planned clinical trials; the risk that results from exploratory endpoints, subgroup analyses or other analyses may not be predictive of future clinical outcomes or treatment effects; that observed trends or improvements in medical or functional outcomes may not be replicated in additional analyses or studies or translate into meaningful long-term clinical benefits; that oral infigratinib may not demonstrate benefits beyond growth or achieve the anticipated clinical, regulatory or commercial profile; that the FDA, EMA or other regulatory authorities may not approve oral infigratinib on the anticipated timeline or at all, including by the FDA's February 4, 2027 PDUFA target action date, or may require additional data, studies or other information; that BridgeBio may not launch oral infigratinib in the U.S. upon approval or on the anticipated timeline; that BridgeBio's planned regulatory submissions, including its planned MAA submission in the fourth quarter of 2026, may be delayed or may not occur as expected; that oral infigratinib may not become the first and only approved oral therapy or a best-in-class option for achondroplasia; and that BridgeBio's plans to further evaluate, share, study or develop oral infigratinib for broader medical and functional impacts or additional skeletal dysplasia conditions may change or may not result in successful development or regulatory approval; the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine and the Middle East, increasing rates of inflation and changing

interest rates, on business operations and expectations, as well as those risks set forth in the Risk Factors section of the Company's most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K and the Company's other filings with the U.S. Securities and Exchange Commission. Moreover, the Company operates 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 the Company's 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, BridgeBio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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Source: BridgeBio Pharma, Inc.