BRIDGEBIO

NEWS RELEASE

Oral Infigratinib Shows Meaningful Benefits Beyond Growth Within 52 Weeks in Children with Achondroplasia in the Phase 3 PROPEL 3 Trial

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

- Stabilization of sleep apnea measures: The mean total Apnea-Hypopnea Index (AHI) at 52 weeks remained consistent with the baseline mean in the oral infigratinib group, with a 10.4% increase, versus a 49.2% increase in the placebo group; in children younger than 8 years of age, the mean total AHI was unchanged for the oral infigratinib group, versus a 63.2% increase in the placebo group

- Reduction in rate of ear infections: The estimated annualized rate of otitis media events was 38% lower in the oral infigratinib group compared to the placebo group; in children younger than 8 years of age, the annualized rate of otitis media events was 47% lower in the oral infigratinib group compared to the placebo group

- In children treated for up to three years in the PROPEL program, oral infigratinib demonstrated sustained improvements in growth (CFBL in height Z-score of +0.92 SD at Year 3) and body proportionality (CFBL in upper-to-lower body segment ratio of -0.15 at Year 3), with a well-tolerated safety profile and no new safety signals

- These findings build on the previously reported PROPEL 3 primary and secondary endpoint results published in NEJM, in which oral infigratinib demonstrated a +2.10 cm/year improvement in AHV versus placebo ($p<0.0001$) and a statistically significant improvement in body proportionality within 52 weeks in children younger than 8 years of age

- BridgeBio submitted an NDA to the FDA for oral infigratinib in achondroplasia and anticipates a U.S. launch in mid-2027

PALO ALTO, Calif., Sept. 09, 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 presented new exploratory analyses from PROPEL 3, the global Phase 3 pivotal study of oral infigratinib in children living with achondroplasia, showing directionally favorable trends beyond growth across medical complications associated with achondroplasia, including sleep apnea, otitis media, and body composition. These data were presented at the Annual European Society for Paediatric Endocrinology (ESPE) Meeting 2026 in Marseille, France, in a late-breaking oral presentation by Julie Hoover-Fong, M.D., Ph.D. of Johns Hopkins University, U.S.

"In the past, achondroplasia research has focused largely on measuring growth because height can be readily determined. But families have consistently emphasized that their priorities extend well beyond the growth chart," said Melita Irving, M.D. of Guy's and St Thomas' NHS Foundation Trust, London, UK. "Growth is only one part of the picture of this medically complicated condition in which children experience disrupted sleep, recurring ear infections, or other health challenges associated with achondroplasia. What I find especially encouraging here is not only the consistent benefit observed across each measure, but that the longer-term data from the PROPEL program show improvements in growth and body proportionality sustained through three years of treatment, and a safety profile that remained favorable with no new safety signals identified. Taken together, these findings suggest there is potential to address a broader range of outcomes that may meaningfully affect a child's health and daily life over time."

The new exploratory results from PROPEL 3 shared at ESPE 2026 include:

- Stabilization of sleep apnea measures:
  - The mean total apnea-hypopnea index (AHI) at 52 weeks remained consistent with the baseline mean in the oral infigratinib group, with a 10.4% increase, versus a 49.2% increase in the placebo group
  - In children younger than 8 years of age, the mean total AHI at 52 weeks was unchanged for the oral infigratinib group, versus a 63.2% increase for the placebo group
- Reduction in rate of ear infections: The estimated annualized rate of otitis media, a recurrent complication in children with achondroplasia that can affect hearing and speech development, was 38% lower in the oral infigratinib group compared to the placebo group, and in children younger than 8 years of age, 47% lower in the oral infigratinib group compared to the placebo group
- Impact on body composition: Mean change from baseline in body mass index was smaller in the oral infigratinib group compared to placebo (0.50 versus 0.93 kg/m^2), with a greater increase in lean body mass

(1.77 versus 1.58 kg) and smaller increases in body fat mass (0.95 versus 1.12 kg) and visceral fat volume (1.55 versus 18.42 mL) compared to placebo

In addition to the late-breaking oral presentation at the Annual ESPE Meeting 2026, BridgeBio shared a poster, Longer-Term Efficacy and Safety Results of Infigratinib in Children with Achondroplasia, presented by Dr. Irving. These findings showed that in children treated for up to three years in the PROPEL program, oral infigratinib demonstrated sustained improvements in growth, with a change from baseline in height Z-score relative to the achondroplasia population of +0.92 SD at Year 3. Additionally, oral infigratinib demonstrated sustained improvements in proportionality, with a change from baseline in upper-to-lower body segment ratio of -0.15 at Year 3. Results showed that oral infigratinib continued to be well-tolerated, with no new safety signals identified.

BridgeBio also shared one poster focused on PROPEL Infant & Toddler (I&T), an ongoing Phase 2/2b study in children under 3 years old with achondroplasia and one eposter focused on qualitative research on the impacts of hypochondroplasia.

PROPEL 3 demonstrated best-in-class improvements in annualized height velocity (AHV) and, for the first time in a Phase 3 achondroplasia study, statistically significant improvements in body proportionality and arm span, supporting its potential as the first oral targeted therapeutic option that directly impacts FGFR3. The topline results can be found **here**. These data were published as an original research article in the New England Journal of Medicine (NEJM) 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**.

BridgeBio believes oral infigratinib is positioned to become the first and only approved oral therapy and a potential best-in-class option for children living with achondroplasia. The Company submitted an NDA to the FDA for oral infigratinib in achondroplasia and anticipates a U.S. launch in mid-2027. The Company 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 U.S. FDA based on the shared results from the PROPEL 2 clinical trial, which meet the FDA's requirement of potentially demonstrating substantial improvement in efficacy over available therapies on clinically significant endpoints. In addition to receipt of Breakthrough Therapy Designation, oral infigratinib has also received Orphan Drug Designation, Fast Track Designation, and Rare Pediatric Disease Designation for achondroplasia from the FDA. If oral infigratinib is approved, BridgeBio may qualify for a Priority Review Voucher.

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.

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

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, or the negative of these terms or other comparable terminology are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these

identifying words. BridgeBio intends 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 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 BridgeBio's anticipated U.S. launch in mid-2027; BridgeBio's plans to submit a Marketing Authorization Application for oral infigratinib in achondroplasia to the European Medicines Agency in the second half of 2026; BridgeBio's potential eligibility to receive a Priority Review Voucher if oral infigratinib is approved; 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, or may require additional data, studies or other information; that BridgeBio may not launch oral infigratinib in the U.S. in mid-2027 or on the anticipated timeline; that BridgeBio's planned regulatory submissions, including its planned MAA submission, 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; that BridgeBio may not qualify for or receive a Priority Review Voucher; and that BridgeBio's plans to 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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