

BridgeBio Reports Positive Phase 3 Topline Results for Oral Infigratinib with the First Statistically Significant Improvements in Body Proportionality in Achondroplasia

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- PROPEL 3 successfully met the primary endpoint of change from baseline in AHV at Week 52 ($p<0.0001$)
- Change from baseline in AHV was superior to placebo at Week 52 with a mean treatment difference against placebo of +2.10 cm/year; the LS mean was +1.74 cm/year
- 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)
- 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
- Oral infigratinib was well tolerated, with no discontinuations or serious adverse events related to study drug, 3 cases (4%) of hyperphosphatemia considered mild and transient with not a single case requiring either dose reduction or discontinuation, and no adverse events associated with inhibition of FGFR1 or 2 (e.g., retinal or corneal)
- NDA and MAA submissions planned in second half of 2026 for achondroplasia; oral infigratinib is the only therapeutic option in development for achondroplasia to have Breakthrough Therapy Designation from the FDA

- Given the strength of these data, BridgeBio plans to accelerate the development of oral infigratinib in hypochondroplasia, and is enrolling the observational run-in for the Phase 3 trial

PALO ALTO, Calif., Feb. 12, 2026 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a biopharmaceutical company focused on developing medicines for genetic conditions, today announced positive topline results from PROPEL 3, the global Phase 3 pivotal study of oral infigratinib in children living with achondroplasia. BridgeBio will host an investor call on February 12, 2026 at 8:00 am ET to discuss these results.

"Achondroplasia is a genetic condition driven by FGFR3 that affects more than stature alone, with consequences on physical functioning and independence that can impact widely over a person's lifetime," said Ravi Savarirayan, M.D., Ph.D. of Murdoch Children's Research Institute in Melbourne, Australia, and global lead investigator for PROPEL 3. "Infigratinib is the first oral therapy designed to target FGFR3 and directly address the underlying cause of achondroplasia. In the broadest age range studied to date, oral infigratinib has demonstrated the highest and most significant improvement in annualized growth velocity, along with the first statistically significant improvement in body proportionality, in children aged 3 to 8 years, reported for any therapy approved or in development for this condition. Taken together, these best-in-class results highlight the transformative potential for infigratinib to address aspects of achondroplasia beyond linear height, and with a product administered orally."

PROPEL 3 was a global, one-year, 2:1 randomized, double-blinded placebo-controlled clinical study, evaluating the efficacy and safety of infigratinib in children with achondroplasia aged 3 to <18 years with open growth plates. Key results from the study through Week 52 include:

- Primary endpoint:
 - Change from baseline in annualized height velocity (AHV) superior to placebo, with an LS mean treatment difference of +1.74 cm/year ($p<0.0001$) and a mean treatment difference of +2.10 cm/year
- Secondary endpoints:
 - Consistent with the primary endpoint, the secondary endpoint of absolute AHV at Week 52 showed a significant improvement with infigratinib compared to placebo, with the infigratinib arm achieving the highest LS mean absolute AHV reported to date in a randomized trial in achondroplasia (5.96 cm/year versus 4.22 cm/year on placebo)
 - Change from baseline in height Z-score (achondroplasia reference population) was superior to placebo, with an LS mean treatment difference of +0.32 SD ($p<0.0001$), the largest difference observed in a randomized trial in achondroplasia; the LS mean change from baseline on the treatment arm was +0.41 SD, the largest improvement observed on a treatment arm in a randomized trial for achondroplasia
 - In a pre-specified exploratory analysis (children younger than 8; >50% of the participants) of the key

secondary endpoint of change from baseline in upper-to-lower body proportionality at Week 52, oral infigratinib is the first therapeutic option to show statistical significance against placebo in a randomized trial for achondroplasia, demonstrating an LS mean decrease of -0.05 against placebo (p<0.05)

- In the overall population, infigratinib achieved an LS mean decrease of -0.05, the largest reduction observed in a treatment arm in a randomized achondroplasia trial, with a favorable LS treatment difference of -0.02 versus placebo at Week 52 (p=0.1849)
- 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)
 - No adverse events associated with CNP analogues: symptomatic hypotension, injection site reactions, or hypertrichosis

"There remains a significant unmet need for therapeutic options that are effective, practical, and less invasive for children living with achondroplasia," said Daniela Rogoff, M.D., Chief Medical Officer, Skeletal Dysplasia of BridgeBio. "The PROPEL 3 data support the potential of an oral medicine directly targeting FGFR3 overactivity to address important clinical needs, while fitting into daily life for families who are seeking a non-injectable option. These results represent meaningful progress for those who have been waiting for a better approach, and we look forward to advancing this program towards global submissions. We would like to thank the study participants, their families, investigators, and study staff who trusted us and joined us on this journey."

Based on these results, BridgeBio intends to meet with regulatory authorities to discuss plans for submission of a New Drug Application (NDA) and Marketing Authorization Application (MAA) for infigratinib in the second half of 2026 to support approval. The Company also intends to accelerate the development of infigratinib for hypochondroplasia, and is enrolling participants in the observational run-in for the Phase 3 trial. The Company also has an ongoing clinical trial of infigratinib for the newborn to <3 year old age groups in achondroplasia in the PROPEL Infant & Toddler trial. Infigratinib has received Breakthrough Designation from the FDA for achondroplasia, as well as Orphan Drug Designation (FDA & EMA), Fast Track Designation, and Rare Pediatric Disease Designation.

"Today's announcement represents another milestone in achondroplasia research and, pending regulatory review, expands available care to include an oral therapeutic option, offering individuals and families additional choice as they consider their healthcare goals and preferences," said Michael Hughes, Chair of the Biotech Industry Liaison Committee at Little People of America. "BridgeBio's commitment to engaging with and learning from the dwarfism community reflects a focus on listening to lived experience and recognizing diverse priorities in shaping research

efforts. Within this context, the observed improvement in body proportionality with one year of treatment in the PROPEL 3 study is an outcome that individuals and families have identified as meaningful, may be relevant to physical function, and continues to be evaluated to understand its broader significance.”

Information about PROPEL Infant & Toddler trial (NCT07169279) can be found [here](#) on [clinicaltrials.gov](#).

Information about ACCEL, the Company’s observational lead-in study for 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 infigratinib in hypochondroplasia, (NCT06873035) can be found [here](#). BridgeBio is committed to exploring the potential of infigratinib on wider medical and functional impacts of achondroplasia, hypochondroplasia and other skeletal dysplasia conditions, which hold significant unmet needs for families.

Webcast Information

BridgeBio will host an investor call and simultaneous webcast to discuss the results from the Phase 3 PROPEL 3 study of infigratinib in children with achondroplasia on February 12, 2026 at 8:00 am ET. A link to the webcast may be accessed from the event calendar page of BridgeBio’s website at <https://investor.bridgebio.com/>. A replay of the conference call and webcast will be archived on the Company’s website and will be available for at least 30 days following the event.

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 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 variant in FGFR3.

About BridgeBio Pharma, Inc.

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. 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 express and implied statements relating to the topline results from PROPEL 3, the global Phase 3 pivotal study of oral infigratinib in children living with achondroplasia, the efficacy, safety and the clinical, therapeutic and market potential of oral infigratinib, our expected interactions with regulatory authorities, our plans to submit a New Drug Application and Marketing Authorization Application for infigratinib to the FDA and EMA, as applicable, in the second half of 2026 for treatment of achondroplasia; our plans to accelerate the development of oral infigratinib in hypochondroplasia, the progress of our ongoing and planned clinical trials of infigratinib for the newborn to <3 year old age groups in achondroplasia in the PROPEL Infant & Toddler trial, the statements regarding the potential clinical benefits of oral infigratinib for patients with achondroplasia in the quotes of Dr. Savarirayan, Dr. Rogoff and Mr. Hughes, and our commitment to exploring the potential of infigratinib on wider medical and functional impacts of achondroplasia, hypochondroplasia and other skeletal dysplasia conditions, 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 preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations our product candidates are designed to treat not being as large as anticipated, 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, future regulatory filings, approvals and/or sales, despite having ongoing and future interactions with the FDA or other regulatory agencies to discuss potential paths to registration for our product candidates, the FDA or such 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 continuing success of our collaborations, our ability to obtain additional funding, potential volatility in our share price, the impacts of current macroeconomic and geopolitical events, including changing conditions from the hostilities in Ukraine and in Israel and the Gaza Strip, increasing rates of inflation and changing interest rates, on our overall 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, subsequent Quarterly Reports on Form 10-Q and our other filings with the U.S. Securities and Exchange Commission. 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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