

BridgeBio Announces Publication in the New England Journal of Medicine of Phase 3 PROPEL 3 Trial of Oral Infigratinib in Children Living with Achondroplasia

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- Phase 3 PROPEL 3 data published today in NEJM were simultaneously presented at ICCBH in a late-breaking oral presentation; presentation includes new arm span Z-score data showing a statistically significant improvement versus placebo (LS mean +0.37 SD; $p < 0.0001$), the first and only statistically significant placebo-controlled arm span result reported for an achondroplasia trial at 52 weeks
- This is the first and only Phase 3 data for an achondroplasia clinical study published in The New England Journal of Medicine (NEJM), marking BridgeBio's second NEJM publication in achondroplasia and fourth NEJM publication overall in the last three years
- The data includes the largest mean increase in AHV compared to placebo reported in any Phase 3 achondroplasia study (+2.1 cm/year observed mean improvement)
- Oral infigratinib is the only therapy to demonstrate statistically significant improvement in body proportionality in a Phase 3 achondroplasia study, with a LS mean treatment difference of -0.05 in children ages 3 to 8 years ($p < 0.05$)
- Oral infigratinib was well tolerated, with no discontinuations or serious adverse events related to study drug
- BridgeBio intends to submit an NDA to the FDA in the third quarter of 2026 with launch anticipated in early to mid 2027, and an MAA to the EMA in the second half of 2026

PALO ALTO, Calif., June 28, 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 that positive results from PROPEL 3, the global Phase 3 pivotal study of oral infigratinib in children living with achondroplasia, were published as an original research article in the **New England Journal of Medicine (NEJM)**. These data were also presented at the International Congress of Children's Bone Health (ICCBH) 2026 in a late-breaking oral presentation by Ravi Savarirayan, M.D., Ph.D. of Murdoch Children's Research Institute, Melbourne, AUS, and global lead investigator for PROPEL 3.

"The publication of our pivotal trial data (PROPEL 3) in the New England Journal of Medicine is a defining milestone for the field of skeletal dysplasia that reflects the years of rigorous clinical investigation from investigators and dedication from children and their families to make this breakthrough science possible. These remarkable data establish oral infigratinib as the first therapy to directly target FGFR3, deliver the highest treated annualized growth velocity and greatest improvement in body proportionality reported for any current therapy for children with achondroplasia. Presenting these late-breaking data at ICCBH reflects the significance of having an orally administered, mechanistically distinct treatment option that addresses achondroplasia and hypochondroplasia at their very source," said Dr. Savarirayan. "I believe that we are on a clear path toward a best-in-class therapy for children with achondroplasia that families seeking better options are excited to have available to them."

The positive results shared in NEJM from PROPEL 3 include:

- PROPEL 3 successfully met the primary endpoint of change from baseline in annualized height velocity, with a LS mean treatment difference against placebo of +1.74 cm/yr ($p < 0.0001$). The observed mean difference was +2.10 cm/yr ($p < 0.0001$). Both values are the largest observed in a Phase 3 clinical study in achondroplasia
- 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
- 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)
- 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)
- Additional data presented at ICCBH showed infigratinib improved arm span vs. placebo by +0.37 SD ($p < 0.0001$), marking the first statistically significant improvement in arm span from a placebo-controlled

achondroplasia trial

In addition to the late-breaking oral presentation at ICCBH 2026, one oral presentation, one poster, and three encore posters were shared. The new details shared included:

- Health-Related Quality of Life in Children with Achondroplasia: Findings from the Observational PROPEL Study, presented by Marie-Eve Robinson, M.D., of Shriners Hospital for Children Canada, McGill University, Montreal, CA
 - Results from the global observational PROPEL study demonstrated that children with achondroplasia experience reduced health-related quality of life across multiple patient-reported measures, particularly in physical functioning, reinforcing the significant day-to-day burden of the condition and providing important baseline context for future studies of oral infigratinib
- Qualitative Research to Evaluate the Content Validity and Relevance of Patient-Reported Outcome Measures for Children and Parents of Children with Hypochondroplasia, presented by Chandler Crews of The Chandler Project, U.S.
 - Findings from interviews with children and parents affected by hypochondroplasia demonstrated that commonly used patient-reported outcome measures were clear, relevant, and reflective of the real-world physical, cognitive, and quality-of-life challenges experienced by children living with the condition, supporting their use in future clinical research and care

BridgeBio believes oral infigratinib is positioned to become the first approved oral therapy and a potential best-in-class option for children living with achondroplasia and hypochondroplasia. The Company intends to submit an NDA for achondroplasia to the FDA in the third quarter of 2026, and an MAA for achondroplasia to the EMA in the second half of 2026. The Company anticipates a U.S. launch in early to mid 2027.

Oral infigratinib has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (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 infigratinib is approved, BridgeBio may qualify for a Priority Review Voucher.

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 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 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 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 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](https://www.bridgebio.com) and follow us on [LinkedIn](#), [X](#), [Facebook](#), [Instagram](#), [YouTube](#), and [TikTok](#).

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, 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 our expectations regarding the potential approval of oral infigratinib for achondroplasia; the timing of a potential NDA submission to the FDA and MAA submission to the EMA for achondroplasia and a potential launch of oral infigratinib; the potential of oral infigratinib to become the first approved oral therapy and a potential best-in-class option for children living with achondroplasia and hypochondroplasia; the potential of oral infigratinib to address achondroplasia, hypochondroplasia and other skeletal dysplasia conditions at their source and with respect to wider medical and functional impacts; the potential use of findings from our observational and qualitative research in future clinical research and care; and our potential qualification for a Priority Review Voucher if oral infigratinib is approved, 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 the Middle East, 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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