BRIDGEBIO

NEWS RELEASE

BridgeBio Submits NDA to FDA for Encaleret for Individuals Living with ADH1

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- Phase 3 CALIBRATE primary results were presented in an oral presentation at the 2026 ECE, demonstrating the rapid and durable benefit of encaleret across key clinical parameters in ADH1

- All pre-specified primary and key secondary efficacy endpoints were met in the Phase 3 CALIBRATE trial; 76% of participants administered encaleret achieved both serum and urine calcium within the respective target ranges at Week 24 compared to 4% when on conventional therapy at Week 4 ($p<0.0001$)

- Encaleret may be eligible for priority review; BridgeBio anticipates U.S. launch in early 2027

- If approved, encaleret could be the first approved therapy specifically indicated for individuals living with ADH1

- BridgeBio also intends to initiate the RECLAIM-HP Phase 3 clinical study of encaleret in chronic hypoparathyroidism in Summer 2026

PALO ALTO, Calif., May 12, 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 submission of its New Drug Application (NDA) to the FDA for encaleret as a potential targeted treatment for autosomal dominant hypocalcemia type 1 (ADH1).

CALIBRATE, the Phase 3 clinical trial of encaleret in ADH1, successfully achieved all pre-specified primary and key secondary efficacy endpoints, supporting encaleret’s potential as a disease-modifying therapy by targeting the underlying genetic cause of ADH1. The topline results can be found **here.** Additional positive results were presented at the European Congress of Endocrinology (ECE) 2026 in an **oral presentation**, with data showing comprehensive

normalization of mineral homeostasis.

Primary results of the study include:

- 76% of participants randomized to encaleret achieved both target serum calcium and urine calcium levels compared to 4.4% of those same individuals while on standard of care ($p<0.0001$)
- Rapid and sustained improvements in calcium metabolism for participants randomized to encaleret, with increases in serum calcium observed by Day 3 and reductions in urine calcium by Week 3, maintained through Week 24
- At Week 24, more participants randomized to encaleret achieved both target serum and urine calcium levels than participants who remained on standard of care (76% on encaleret vs. 19% on standard of care; $p < 0.0001$)
- Encaleret was observed to restore endogenous parathyroid hormone (91.1% on encaleret vs. 0% of participants on standard of care at Week 24)
- Favorable safety and tolerability profile, with no discontinuations in the encaleret arm and low rates of serious adverse events with frequency similar between treatment arms

“These Phase 3 findings are a landmark moment for the autosomal dominant hypocalcemia type 1 community,” said Filomena Cetani, M.D., Ph.D. of the University of Pisa, Italy. “Encaleret not only has the potential to become the first-ever approved therapy for this rare disease, but it does so by addressing the root cause, restoring normal calcium regulation and lowering the risk of renal complications that individuals on current treatment face every day. Together, these findings exemplify what a first-in-class therapy should look like.”

BridgeBio anticipates a U.S. launch in early 2027. Nearly 2,000 individuals have been diagnosed in the U.S. with autosomal dominant hypocalcemia (ADH) since October 2023 based on claims data, suggestive of a growing marketplace and elevated diagnostic suspicion. The Company also intends to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the use of encaleret in ADH1 in the second half of 2026.

BridgeBio is currently enrolling CALIBRATE-PEDS (**NCT07080385**), a global registrational Phase 2/3 study of encaleret in pediatric ADH1. The Company also plans to initiate RECLAIM-HP, a global Phase 3 study of encaleret in chronic hypoparathyroidism in Summer 2026, building on the Phase 2 proof-of-concept findings of PTH-independent effects of encaleret on renal calcium handling and expanding the potential applications of encaleret beyond ADH1.

About Encaleret
Encaleret is an investigational, orally administered small molecule under investigation to treat ADH1 and chronic

hypoparathyroidism, that is designed to selectively negatively modulate the calcium sensing receptor. Encaleret has been granted Fast Track Designation by the U.S. FDA and Orphan Drug Designation in the U.S., European Union, and Japan.

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. 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 express and implied statements relating to the Company’s expectations regarding the regulatory review process, potential approval, timing of a potential launch for encaleret in ADH1, potential regulatory submissions outside the United States, including the timing of a potential Marketing Authorization Application submission to the European Medicines Agency for encaleret in ADH1, and the potential market opportunity for encaleret, including the size of the diagnosed patient population and future diagnostic rates; the potential for encaleret to become a disease-modifying therapy by targeting the underlying genetic cause of ADH1 and for it to be the first-ever approved therapy for ADH1; the anticipated regulatory pathway for encaleret; and the Company’s plans and expectations regarding the development of encaleret in additional populations and indications, including pediatric ADH1 and chronic hypoparathyroidism. Such statements reflect the Company’s current views about the Company’s plans, intentions, expectations and strategies, which are based on the information currently available to it and on assumptions the Company has made. 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 and success of ongoing and planned 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 the Company's product candidates, the FDA, EMA or such other regulatory agencies not agreeing with the Company's regulatory approval strategies, components of the Company's filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, regulatory submissions for encaleret not being accepted, reviewed or approved on anticipated timelines or at all, encaleret not becoming the first approved therapy specifically indicated for ADH1, estimates regarding the diagnosed patient population, market opportunity and diagnostic trends not proving accurate, the Company's planned studies, including CALIBRATE-PEDS and RECLAIM-HP, being delayed or not proceeding as expected, the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine and in Israel 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.

BridgeBio Media Contact:
Bubba Murarka, Executive Vice President
contact@bridgebio.com
(650)-789-8220

BridgeBio Investor Contact:
Chinmay Shukla, Senior Vice President, Strategic Finance
ir@bridgebio.com

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