



NEWS RELEASE

BridgeBio Reports Positive Phase 3 Topline Results for Encaleret in Patients with Autosomal Dominant Hypocalcemia Type 1

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- The CALIBRATE study of encaleret for patients with ADH1 met all pre-specified primary and key secondary efficacy endpoints
- The primary endpoint was met with 76% of participants administered encaleret achieving both serum and urine calcium within the respective target ranges at Week 24 compared to 4% when on conventional therapy at Week 4 ($p < 0.0001$)
- In a key secondary analysis, 91% of participants administered encaleret achieved intact PTH above the lower limit of the reference range at Week 24 compared to 7% of participants when on conventional therapy at Week 4 ($p < 0.0001$)
- Encaleret was well-tolerated with no discontinuations related to study drug
- NDA submission planned in the first half of 2026 to support full approval
- BridgeBio plans to initiate registrational studies of encaleret in chronic hypoparathyroidism and pediatric ADH1 in 2026

PALO ALTO, Calif., Oct. 29, 2025 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a new type of biopharmaceutical company focused on genetic diseases, today announced positive

topline results from CALIBRATE, its global Phase 3 study of encaleret in autosomal dominant hypocalcemia type 1 (ADH1). BridgeBio will host an investor call on October 29, 2025 at 8:00 am ET to discuss these results.

CALIBRATE was designed to study the efficacy and safety of encaleret, an investigational, orally-administered, negative allosteric modulator of the calcium-sensing receptor (CaSR). The primary endpoint, defined as the proportion of participants randomized to receive encaleret achieving both serum calcium (8.3-10.7 mg/dL) and urine calcium (<300 mg/day for males and <250 mg/day for females) in the respective target ranges, was achieved by 76% of encaleret-treated participants (34 of 45) compared to 4% for these same participants (2 of 45) while on conventional therapy (p-value <0.0001).

"The remarkable results of the landmark CALIBRATE study represent an important step forward for patients living with ADH1," said Michael Mannstadt, M.D., Chief of the Endocrine Unit at the Massachusetts General Hospital.

"Unlike conventional therapy with calcium supplements and active vitamin D, encaleret not only increased and maintained both blood calcium and endogenous parathyroid hormone (PTH) but also decreased and maintained urine calcium in the normal range. The consistent and clinically meaningful improvements in calcium and mineral homeostasis indicate its potential to become an important new standard of care for this patient community."

"ADH1 is one of the most common genetic causes of hypoparathyroidism, representing a unique form of the condition and a distinct community within HPA that we serve. People living with ADH1 often face daily challenges managing low blood calcium and high urinary calcium, which can lead to seizures, tetany, heart rhythm disturbances, brain calcifications, kidney stones, and kidney damage or failure. BridgeBio's CALIBRATE Phase 3 results are promising and offer potential for a targeted therapy for people living with ADH1, including those yet to be diagnosed," said Patty Keating, Executive Director of the HypoPARAthyroidism Association (HPA).

The CALIBRATE study enrolled 70 adults with ADH1 and randomized 67 participants in a 2:1 ratio (encaleret: standard of care). The pre-specified key secondary analyses comparing encaleret to standard of care included a between group comparison on the proportion of participants achieving both target albumin-corrected serum and urine calcium (p<0.0001), and comparisons of intact PTH above the lower limit of the reference range (p<0.0001). Additional results from the clinical trial include:

- By Day 3 after randomization, 71% (32 of 45) of participants assigned to encaleret had an albumin-corrected serum calcium within the reference range
- At the end of the titration Period (Week 20), 98% (44 of 45) of participants receiving encaleret had an albumin-corrected serum calcium in the target range, compared with 33% (7 of 21) of participants on conventional therapy
- Among encaleret responders at Week 24, none required conventional therapy during Period 3¹
- Encaleret achieved a mean increase in change from baseline of corrected calcium by 0.82 mg/dL from Week 4

to Week 24 ($p < 0.0001$)

- Encaleret achieved a mean reduction in change from baseline of 200 mg/day in 24-hour urine calcium from Week 4 to Week 24 ($p < 0.0001$)
- Encaleret was well-tolerated; safety findings were generally consistent with known ADH1 biology or related to the mechanism of action of encaleret

65 of 67 randomized participants (97%) elected to continue in the ongoing long-term extension of the study.

"Our deepest gratitude goes out to the patients, their caregivers, investigators, and study staff who have made this groundbreaking CALIBRATE study possible and continue to contribute to this pivotal research in ADH1," said Scott H. Adler, M.D., Chief Medical Officer of Calcilytix, a BridgeBio affiliate that is focused on developing encaleret. "We are extremely encouraged by the robust and positive findings of this registrational study, which underscore the potential for encaleret to meaningfully improve the lives of people living with ADH1. We look forward to working closely with health authorities to bring encaleret to patients as quickly as possible."

The Company intends to submit its New Drug Application (NDA) to the FDA in the first half of 2026, and a Marketing Authorization Application to the EMA to follow. In addition, BridgeBio plans to initiate a registrational trial of encaleret in pediatric ADH1 in Q1 2026 and a Phase 3 study of encaleret in adults with chronic hypoparathyroidism in 2026.

¹Requirement for conventional therapy defined as oral calcium > 600 mg/day and/or active vitamin D during Period 3.

Webcast Information

BridgeBio will host an investor call and simultaneous webcast to discuss the results from the Phase 3 CALIBRATE study of encaleret in patients with ADH1 on October 29, 2025, 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 Encaleret

Encaleret is an investigational, orally administered small molecule under investigation to treat ADH1, that is designed to selectively negatively modulate the calcium sensing receptor, targeting ADH1 at its source. Encaleret has received Fast Track Designation by the U.S. FDA and Orphan Drug Designation in the U.S., European Union, and Japan.

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (BridgeBio) is a new type of biopharmaceutical company founded to discover, create, test, and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information visit **bridgebio.com** and follow us on **LinkedIn, X, Facebook, Instagram, and YouTube.**

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 the Phase 3 topline results for encaleret in patients with ADH1, the efficacy, safety and the clinical and therapeutic potential of encaleret, our plans to submit a New Drug Application for encaleret to the FDA in the first half of 2026, and to apply for Marketing Authorization Application to the EMA; our plans to initiate registrational studies of encaleret in chronic hypoparathyroidism and pediatric ADH1 in 2026, and the statements regarding the potential clinical benefits of encaleret for patients in the quotes of Dr. Mannstadt, Ms. Keating and Dr. Adler, 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, 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, including through less dilutive sources of

capital than equity financings, potential volatility in our share price, the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine and in Israel and the Gaza Strip, 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 our most recent Annual Report on Form 10-K and the Company's other subsequent 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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