BRIDGEBIO

NEWS RELEASE

BridgeBio Announces FDA Acceptance of NDA for Encaleret for ADH1

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- PDUFA target action date of May 8, 2027

- If approved, encaleret will be the first and only approved therapy specifically indicated for individuals living with ADH1, representing a potential blockbuster opportunity for BridgeBio

- Encaleret demonstrated consistent efficacy across all pre-specified primary and key secondary efficacy endpoints normalizing key markers of CaSR-driven disease biology without the need for calcium and vitamin D supplements, with a favorable safety and tolerability profile

- BridgeBio is also currently enrolling CALIBRATE-PEDS, a registrational Phase 2/3 trial to study encaleret in pediatric ADH1 and intends to initiate the RECLAIM-HP Phase 3 registrational study of encaleret in chronic hypoparathyroidism later this summer; successful development could extend encaleret's utility to a broader patient population

PALO ALTO, Calif., July 22, 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 FDA has accepted for filing its New Drug Application (NDA) for encaleret for the treatment of individuals living with autosomal dominant hypocalcemia type 1 (ADH1). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 8, 2027, and BridgeBio is prepared to launch encaleret upon approval, representing a potential blockbuster opportunity for the Company. The FDA also notified the Company that it is not currently planning to hold an advisory committee meeting to discuss the application.

"The FDA's acceptance of our NDA is a powerful validation of encaleret's differentiated clinical profile and enables a

major step forward for the ADH1 community. We believe encaleret has the potential to transform care for patients who currently have no indicated treatment options, and we're moving with urgency to bring it to them," said Ananth Sridhar, Chief Executive Officer of BridgeBio Endocrinology.

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 results were **presented** at the European Congress of Endocrinology (ECE) 2026 and the Endocrine Society 2026 annual meeting (ENDO) in oral presentations, with data showing simultaneous restoration of blood and urine calcium, as well as restoration of physiologic parathyroid hormone (PTH) production.

"For too long, ADH1 has been an invisible condition, that disrupts several systems in the body, from the kidneys to the nervous system to the muscles and often goes unrecognized for years. The path to diagnosis is frequently a long and exhausting one, especially for patients with a genetic disorder. Patients often cycle through specialists before anyone connects the dots to their diagnosis. The FDA's acceptance of this NDA is a moment of real hope for ADH1 patients and a signal that the medical and regulatory community understand the seriousness of this condition and that an orally administered option may finally be on the horizon for those in need," said Patty Keating, Executive Director of the HypoPARAthyroidism Association.

As of April 2026, over 2,100 individuals have been diagnosed in the U.S. with autosomal dominant hypocalcemia 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 later this summer, building on the positive 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. Successful development could extend encaleret's utility to a broader patient population.

About Autosomal Dominant Hypocalcemia Type 1 (ADH1)
ADH1 is a common form of genetic hypoparathyroidism caused by gain-of-function variants in the calcium-sensing receptor gene (CASR). The calcium-sensing receptor (CaSR) constantly monitors and balances blood calcium levels by regulating parathyroid hormone secretion and calcium reabsorption in the kidneys. Individuals with ADH1 typically experience hypocalcemia, hypercalciuria, and inappropriately low levels of PTH. Symptoms of hypocalcemia may include severe muscle cramps, muscle spasms (tetany), a burning or prickling sensation in the hands or feet (paresthesia), brain fog, fatigue, and seizures. Hypercalciuria may result in kidney calcification

(nephrocalcinosis), kidney stones (nephrolithiasis), and kidney failure.

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 for encaleret in ADH1, including the FDA’s review of the NDA and the potential for approval; the Company’s preparedness to launch encaleret upon approval; the potential for encaleret to become the first and only approved therapy specifically indicated for individuals living with ADH1 and to transform care for patients with ADH1; the potential for encaleret to be a disease-modifying therapy by targeting the underlying genetic cause of ADH1; the potential commercial opportunity for encaleret in ADH1, including as a potential blockbuster opportunity for the Company; the timing of a potential Marketing Authorization Application submission to the European Medicines Agency for encaleret in ADH1; the Company’s plans to initiate RECLAIM-HP, a global Phase 3 study of encaleret in chronic hypoparathyroidism, and the potential expansion of encaleret beyond ADH1, including the potential for encaleret to become a multi-billion-dollar opportunity for the Company. 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 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 not being accepted or approved on anticipated timelines or at all, encaleret not becoming the first and only approved therapy specifically indicated for individuals living with ADH1, the Company not being successful in launching encaleret on anticipated timing or at all, the potential commercial opportunity for encaleret not being realized, the Company's plans for RECLAIM-HP 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 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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