NEWS RELEASE

bridgebio announces commercial progress, program updates, and 2025 milestones

2025-01-13

- Remarkable early Attruby demand: 430 scripts written by 248 unique HCPs since FDA approval with broad uptake across academic centers and community centers in all patient types

- Fully enrolled three major market Phase 3 clinical trials: FORTIFY (BBP-418 for LGMD2I/R9); CALIBRATE (encaleret for ADH1); and PROPEL 3 (infigratinib for Achondroplasia)

- Well-financed to launch Attruby and read out major market Phase 3 trials: $406M in cash as of last quarter, received $500M upon acoramidis FDA approval from royalty facility, and anticipate $105M in regulatory milestones in 1H 2025 from acoramidis Europe and Japan approvals

PALO ALTO, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (“BridgeBio” or the “Company”), a new type of biopharmaceutical company focused on genetic diseases, today provided updates on its commercial progress for Attruby (acoramidis), status of late-stage pipeline programs, and anticipated 2025 milestones.

“With the FDA’s approval of Attruby, we marked an important moment for both our organization and the broader ATTR-CM patient community in need of new treatment options. We’re grateful for the enthusiasm surrounding the product and the associated initial commercial momentum, with 430 prescriptions written by 248 unique physicians, and we look forward to continued progress,” said Neil Kumar, Ph.D., Founder and CEO of BridgeBio. “Additionally, we are excited to share that we have completed enrollment of all three of our major market Phase 3 clinical trials. I look forward to continuing to work with this stellar team to serve patients with genetic disease in 2025.”

Business Update

On November 22, 2024, the U.S. Food and Drug Administration (FDA) approved Attruby (acoramidis), a near-complete TTR stabilizer (≥90%), to reduce cardiovascular death and cardiovascular-related hospitalization in adult patients with ATTR-CM, a progressive fatal disease presenting as an infiltrative, restrictive cardiomyopathy resulting in heart failure.

Since the approval, BridgeBio has seen remarkable momentum with 430 patient prescriptions written by 248 physicians.

Pipeline Updates

BBP-418 – Glycosylation substrate for limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9):

- FORTIFY is a Phase 3 clinical trial of BBP-418 in LGMD2I/R9, a rare genetic disorder caused by variants in the fukutin-related protein (FKRP) gene that result in progressive muscle degeneration and damage, and eventual loss of functional independence. The trial is fully enrolled with 112 patients.
- The Company expects Last Patient – Last Visit (LPLV) and topline readout of the interim analysis cohort in second half 2025.
- If successful, BBP-418 would be the first approved therapy for individuals living with LGMD2I/R9.

Encaleret – Calcium-sensing receptor (CaSR) antagonist for autosomal dominant hypocalcemia type 1 (ADH1):

- CALIBRATE, the Phase 3 clinical trial of encaleret in ADH1, a rare, genetic form of hypoparathyroidism, is fully enrolled with 70 patients. The trial is designed to evaluate the efficacy and safety of encaleret compared to standard of care in adult patients with ADH1.
- The Company expects Last Patient – Last Visit and topline readout in second half 2025.
- If successful, encaleret would be the first approved therapy for individuals living with ADH1.

Infigratinib – FGFR1-3 inhibitor for achondroplasia and hypochondroplasia:

- PROPEL 3, the Phase 3 clinical trial of infigratinib in achondroplasia, the most common form of disproportionate short stature, is fully enrolled with 114 participants.
- The Company expects Last Participant – Last Visit in second half 2025.
- If successful, infigratinib would be the first approved oral therapy for children living with achondroplasia.

2025 Milestones

Program	Status	Anticipated 2025 Milestone
Acoramidis for ATTR-CM	US FDA approval on November 22, 2024	EU and Japan approvals in 1H 2025
BBP-418 for LGMD2I/R9	FORTIFY, Phase 3 study enrollment completed	Last Patient – Last Visit and Topline readout in 2H 2025
Encaleret for ADH1	CALIBRATE, Phase 3 study enrollment completed	Last Patient – Last Visit and Topline readout in 2H 2025
Infigratinib for achondroplasia	PROPEL 3, Phase 3 study enrollment completed	Last Participant – Last Visit in 2H 2025

About Attruby™ (acoramidis)

INDICATION

Attruby is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Diarrhea (11.6% vs 7.6%) and upper abdominal pain (5.5% vs 1.4%) were reported in patients treated with Attruby versus placebo, respectively. The majority of these adverse reactions were mild and resolved without drug discontinuation. Discontinuation rates due to adverse events were similar between patients treated with Attruby versus placebo (9.3% and 8.5%, respectively).

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**, **Twitter** and **Facebook**.

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. 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, including express and implied statements relating to the Company's expectations regarding the commercial success of Attruby; the Company's clinical trials, including the timing of the last patient-last visit and topline data readouts for each of FORTIFY, CALIBRATE and PROPEL 3; the potential for encaleret to become a new treatment for ADH1; the potential for BBP-418 to become a new treatment for LGMD2I/R9; the potential for infigratinib to become a new treatment for achondroplasia; timing of approval of Attruby for ATTR-CM in the European Union and Japan; and the Company's preliminary and unaudited estimate of cash and the Company's anticipated funding of its current operations and related timelines; and the Company's expectations regarding reaching regulatory milestones and receipt of milestone payments, among others, reflect the Company's current views about the Company's plans, intentions, expectations and strategies, which are based on the information currently available to us 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 preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations the Company's 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 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, the continuing success of the Company's collaborations, the Company's ability to obtain additional funding, including through less dilutive sources of capital than equity financings, potential volatility in the Company's 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 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, EVP Communications
contact@bridgebio.com
(650)-789-8220