

BridgeBio Submits NDA to FDA for BBP-418 for Individuals Living with LGMD2I/R9

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- Comprehensive submission includes interim Phase 3 FORTIFY data demonstrating BBP-418's rapid, consistent treatment effect and favorable safety profile, with statistically significant and clinically meaningful improvements in ambulation and pulmonary function
- Based on ongoing discussions with the FDA, BridgeBio anticipates approval with a U.S. launch anticipated in late 2026/early 2027
- If approved, BBP-418 has the potential to become the first and only therapy for individuals living with LGMD2I/R9 and may represent the first approved treatment for any form of LGMD

PALO ALTO, Calif., March 30, 2026 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a biopharmaceutical company focused on developing medicines for genetic conditions, today announced the submission of its New Drug Application (NDA) to the FDA for oral BBP-418 for the treatment of individuals living with limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9).

"This NDA submission brings us one step closer to delivering the first approved therapy to individuals and families affected by LGMD2I/R9, a severe, progressive neuromuscular disease," said Christine Siu, Chief Executive Officer of BridgeBio Neuromuscular. "This achievement not only reflects the strength of the data, but also our dedicated focus on addressing the urgency of a community that has long been waiting for meaningful treatment options. We are committed to working closely with the FDA to make this potential disease-modifying therapy available as quickly as possible."

FORTIFY, the Phase 3 clinical trial of BBP-418, successfully met all pre-specified primary and secondary endpoints of

its 12-month interim analysis. The topline results can be found [here](#). Additional positive results demonstrating the rapid and consistent treatment effect and favorable safety profile of BBP-418 were presented earlier this month at the 2026 MDA Clinical and Scientific Conference in a late-breaking oral presentation, which can be found [here](#).

BridgeBio anticipates a U.S. launch following FDA approval in late 2026/early 2027. If successful, BBP-418 would be the first and only approved therapy for individuals living with LGMD2I/R9, potentially representing the first approval of a therapy for any form of LGMD. The Company is also engaging regulatory agencies to identify an expedited path to approval for BBP-418 in Europe.

BBP-418 has previously received Orphan Drug, Fast Track, and Rare Pediatric Disease Designations from the FDA and Orphan Drug Designation from the European Medicines Agency (EMA). With Fast Track designation and the potential for BBP-418 to address unmet need in LGMD2I/R9, the NDA for BBP-418 may be eligible for Priority Review. Consistent with Rare Pediatric Designation from the FDA, if BBP-418 is approved, BridgeBio may qualify for a Priority Review Voucher. The Company intends to initiate clinical studies of BBP-418 in LGMD2I/R9 for individuals less than 12 years of age and in LGMD2M/2U in the near future.

About Limb-Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)

LGMD2I/R9 is a monogenic autosomal recessive disease caused by partial loss of function mutations in the fukutin-related protein (FKRP) gene, and FKRP mutations impair glycosylation of alpha-dystroglycan (α DG), a protein associated with stabilizing muscle cells. Clinical manifestations typically present as a skeletal myopathy affecting the lower and then upper limbs, which is commonly later accompanied by pulmonary muscle and cardiac muscle involvement. Individuals who harbor a homozygous L276I genotype typically develop disease manifestations during late childhood with progression to loss of independent ambulation (25%), assisted ventilation (10%), and cardiomyopathy (30%) in adulthood. Cardiomyopathy is progressive, with an annual loss of 0.4% of left ventricular ejection fraction (LVEF). Individuals with other FKRP genotypes typically have an earlier childhood onset with a more severe clinical course, rapid loss of mobility by 20 years of age, more frequent cardiac involvement (60%), and eventual pulmonary decline by 30 years of age in nearly all cases.

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](https://www.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, and timing of a potential launch for BBP-418 in LGMD2I/R9; the Company’s expectations regarding the initiation and timing of clinical trials of BBP-418 in LGMD2I/R9 for individuals less than 12 years of age and in LGMD2M/2U; the potential for BBP-418 to become the first and only approved therapy for LGMD2I/R9 and potentially the first approved therapy for any form of LGMD; the anticipated regulatory pathway for BBP-418; and the potential eligibility of BBP-418 for Priority Review and under the Rare Pediatric Disease Priority Review Voucher program, and the related FDA review timeline. 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, 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 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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