Letter to the Community January 12, 2026

BridgeBio Reports Additional Positive Results for Small Molecule BBP-418 in Phase 3 LGMD2I/R9 FORTIFY Study

ML Bio Solutions Inc. (ML Bio), a BridgeBio company, is pleased to share additional results from the FORTIFY study as part of a larger update from parent company BridgeBio on company progress, program updates, and 2026 milestones. FORTIFY is a fully enrolled, ongoing Phase 3 study evaluating the safety and efficacy of BBP-418 at 36 months in individuals living with Limb Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9).

As a reminder, data announced in October 2025 showed that the preplanned interim analysis at 12 months showed a highly statistically significant increase in the biomarker glycosylated alpha-dystroglycan[1] (αDG) at 3 months which was sustained at 12 months, as well as improvements in respiratory function and ambulation at 12 months. In addition, there was a decline in serum creatine kinase, a marker of muscle breakdown, in BBP-418 treated individuals. BBP-418 was well tolerated, with no serious safety events related to BBP-418.

New data released at the 44th Annual J.P. Morgan Healthcare Conference from the interim analysis of FORTIFY include the following:

- At 12 months, the data show BBP-418's impact across a broad population, with consistent benefit on glycosylated αDG, serum creatine kinase, ambulation, and pulmonary function, as supported by subgroup analyses.
- An early look at the study's primary endpoint, the North Star Assessment for Limb-Girdle Dystrophies (NSAD), showed a clinically meaningful improvement with BBP-418 at 12 months post-treatment.

Results from the FORTIFY study continue to support the potential for BBP-418 to become the first approved therapy for LGMD2I/R9. ML Bio discussed the interim analysis data with the FDA in December 2025, and the FDA acknowledged that the data appear to "*demonstrate consistent treatment effects on multiple efficacy endpoints*." ML Bio plans to file a New Drug Application (NDA) for approval with the FDA in the first half of 2026.

We are deeply grateful to the continued participation of individuals in the FORTIFY study, their families, the investigators, and other study staff for their dedication. We also thank the broader patient and caregiver community, advocacy partners, and supporters for their trust and collaboration. We will continue to share updates as more information becomes available.

For more information:
- Learn more about the FORTIFY study on clinicaltrials.gov using ID NCT05775848- Visit BridgeBio.com for additional details

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