



BridgeBio Completes Enrollment of FORTIFY, Phase 3 Registrational Study of BBP-418 in Limb-girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)

September 30, 2024

ML Bio Solutions (ML Bio), a BridgeBio company, is pleased to announce on LGMD Awareness Day that the FORTIFY study is fully enrolled. FORTIFY is a Phase 3 study to evaluate the safety and efficacy of long-term administration of BBP-418 in people living with Limb Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9).

The FORTIFY study enrolled more quickly than anticipated and exceeded the target number of study participants. We are grateful to the community and the study investigators for their interest and enthusiasm in our study, which was a key contributor to the enrollment of the study. ML Bio plans to conduct an interim analysis which will look at data from the initial portion of FORTIFY. These results are expected in 2025.

The interim analysis will evaluate a biomarker, glycosylated alpha dystroglycan (α DG) from muscle biopsy tissue, as a potential surrogate endpoint. A surrogate endpoint is a biomarker that may predict clinical benefit. Surrogate endpoints can be more sensitive than traditional endpoints, detecting subtle changes before functional changes can be measured in clinical trials.

ML Bio believes there may be the potential to pursue Accelerated Approval in the U.S. for BBP-418 in LGMD2I/R9 based on the biomarker, glycosylated alpha dystroglycan (α DG).

If successful, BBP-418 may be the first approved therapy for individuals living with LGMD2I/R9. There are currently no approved treatments for individuals living with LGMD2I/R9.





ML Bio is grateful to the FORTIFY study participants, families, and doctors who are helping with the study. We will share more information as it becomes available. Stay tuned for more updates.

For more information:

- You can find more details about the FORTIFY trial on clinicaltrials.gov using the ID NCT05775848.
- You can learn more about LGMD Awareness Day (September 30th) at the [LGMD Awareness Foundation](#).
- You can read the entire BridgeBio press release: BridgeBio Completes Enrollment of FORTIFY, Phase 3 Registrational Study of BBP-418 in Limb-girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9) [here](#).

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