Disc Medicine Provides Update from FDA Type A Meeting for Bitopertin in Erythropoietic Protoporphyria

June 9, 2026

- *Aligned with the FDA that the Phase 3 APOLLO study, if successful, can serve as the basis for CRL response and could potentially support a traditional approval*
- *On track for expected CRL response submission by end of 2026*

WATERTOWN, Mass., June 09, 2026 (GLOBE NEWSWIRE) -- Disc Medicine, Inc. (NASDAQ:IRON), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases, today announced it has completed a Type A meeting with the US Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) to the New Drug Application (NDA) for bitopertin in erythropoietic protoporphyria (EPP). In this meeting, Disc aligned with the FDA that the ongoing Phase 3 APOLLO study, if successful, can serve as the basis for a response to the CRL and could potentially support a traditional approval.

“The discussion with the FDA provided valuable clarity on the path forward for the bitopertin NDA,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc Medicine. “We look forward to reporting results from the APOLLO study later this year and remain committed to advancing bitopertin as a potential treatment option for patients with EPP.”

APOLLO is a double-blind, placebo-controlled Phase 3 study of bitopertin in patients ages 12 and above with EPP and X-linked protoporphyria (XLP), that includes sites in the US, Canada, Europe, and Australia. The co-primary endpoints are average monthly total time in sunlight without pain between 10:00 and 18:00 during the last month of the 6-month treatment period and percent change from baseline in whole blood metal-free PPIX after 6 months of treatment. Data from APOLLO is expected in Q4 2026, after which a CRL response will be submitted with an FDA decision expected by mid-2027.

About Bitopertin
Bitopertin is an investigational, clinical-stage, orally administered inhibitor of glycine transporter 1 (GlyT1) that is designed to modulate heme biosynthesis. GlyT1 is a membrane transporter expressed on developing red blood cells and is required to supply sufficient glycine for heme biosynthesis and support erythropoiesis. Disc is developing bitopertin as a potential treatment for a range of hematologic diseases including erythropoietic porphyrias, where it has potential to be the first disease-modifying therapy. Bitopertin has been studied in multiple clinical trials in patients with EPP, including the Phase 2 open-label BEACON trial, the Phase 2 double-blind, placebo-controlled AURORA trial, an open-label extension HELIOS trial, and the Phase 3 double-blind, placebo-controlled APOLLO trial.

Bitopertin is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide. Disc obtained global rights to bitopertin under a license agreement from Roche in May 2021.

About Disc Medicine

Disc Medicine (NASDAQ:IRON) is a clinical-stage biopharmaceutical company committed to discovering, developing, and commercializing novel treatments for patients who suffer from serious hematologic diseases. We are building a portfolio of innovative, potentially first-in-class therapeutic candidates that aim to address a wide spectrum of hematologic diseases by targeting fundamental biological pathways of red blood cell biology, specifically heme biosynthesis and iron homeostasis. For more information, please visit www.discmedicine.com.

Disc Cautionary Statement Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, express or implied statements regarding: Disc’s expectations with respect to the next stages of its development program for bitopertin, including the projected timelines for the completion of the APOLLO clinical trial and release of data; and the projected timelines for Disc’s response to the FDA’s Complete Response Letter (CRL) and any potential approval decision by the FDA. The use of words such as, but not limited to, “believe,” “expect,” “estimate,” “project,” “intend,” “future,” “potential,” “continue,” “may,” “might,” “plan,” “will,” “should,” “seek,” “anticipate,” or “could” or the negative of these terms and other similar words or expressions that are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Disc’s current beliefs, expectations and assumptions regarding the future of Disc’s business, future plans and strategies, clinical results and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Disc may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and investors should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the

plans, intentions and expectations disclosed in the forward-looking statements as a result of a number of material risks and uncertainties including but not limited to: the adequacy of Disc's capital to support its future operations and its ability to successfully initiate and complete clinical trials; the nature, strategy and focus of Disc; the difficulty in predicting the time and cost of development of Disc's product candidates; Disc's plans to research, develop and commercialize its current and future product candidates; the timing of initiation of Disc's planned preclinical studies and clinical trials; the timing of the availability of data from Disc's clinical trials; Disc's ability to identify additional product candidates with significant commercial potential and to expand its pipeline in hematological diseases; the timing and anticipated results of Disc's preclinical studies and clinical trials and the risk that the results of Disc's preclinical studies and clinical trials may not be predictive of future results in connection with future studies or clinical trials and may not support further development and marketing approval; and the other risks and uncertainties described in Disc's filings with the Securities and Exchange Commission, including in the "Risk Factors" section of Disc's Annual Report on Form 10-K for the year ended December 31, 2025, and in subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement speaks only as of the date on which it was made. None of Disc, nor its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law.

Media Contact

Peg Rusconi
Deerfield Group
peg.rusconi@deerfieldgroup.com

Investor Relations Contact

Christina Tartaglia
Precision AQ
Christina.tartaglia@precisionaq.com