



Disc Medicine Announces Success on All Primary and Secondary Endpoints in the Pivotal Phase 3 APOLLO Trial of Bitopertin in Adults and Adolescents with Erythropoietic Protoporphyria (EPP)

October 19, 2026

- Positive APOLLO trial topline results demonstrated statistically significant and clinically meaningful benefit across all study endpoints
- Successfully met co-primary endpoints of reduction in protoporphyrin IX (PPIX) and increased total time in light
- All secondary endpoint results were also positive and statistically significant, including reductions in phototoxic reactions and improvements on multiple measures of light tolerance
- Exploratory endpoints of quality-of-life improvement were also statistically significant
- Bitopertin was generally well-tolerated with no new safety signals observed in APOLLO
- Disc plans to resubmit an NDA to FDA by end of 2026, with an FDA decision anticipated by mid-2027
- Disc to discuss topline results in a corporate webcast on October 19, 2026 at 8:00am ET

WATERTOWN, Mass., Oct. 19, 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 topline results from the APOLLO Phase 3 trial of bitopertin in erythropoietic protoporphyria (EPP), including X-linked protoporphyria (XLP). The trial met all its primary and secondary endpoints.

"Today represents a potential breakthrough in the science and treatment of EPP," said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc Medicine. "We could not have hoped for a better outcome, and we are grateful to the patients, caregivers, and physicians who have partnered with us throughout the clinical development of bitopertin. We look forward to engaging with regulators with the goal of bringing an important, innovative medicine to this community as efficiently as possible."

"This is the first time a potential treatment for EPP has shown robust evidence of whole blood PPIX reduction alongside unequivocal improvement on important measures of disease severity: increased time in light, reduced phototoxic reactions, and improved Patient Reported Outcome scores," said Herbert L. Bonkovsky, M.D., Director of Gastroenterology & Internal Medicine, Professor Emeritus of Medicine at Wake Forest University School of Medicine, and a Principal Investigator of APOLLO.

"These results are compelling evidence of the clinical benefit of a mechanism aimed at reducing the production of PPIX, the fundamental cause of disease," added Will Savage, M.D., Ph.D., Chief Medical Officer of Disc Medicine. "It has been an incredible journey from establishing the original hypothesis of targeting heme synthesis in cellular models to seeing that biology translate into the clear and meaningful clinical effects from APOLLO. We plan to share more detailed data with additional insights from APOLLO at a future medical conference."

APOLLO is a randomized, double-blind pivotal Phase 3 trial evaluating the safety and efficacy of bitopertin versus placebo in adults and adolescents aged 12 or older with EPP or XLP. The trial enrolled 183 patients across the United States, Canada, Europe, and Australia, who were stratified by baseline light tolerance and geography and randomized 1:1 to receive 60 mg oral bitopertin or placebo once daily for 6 months.

Summary of topline results:

- Bitopertin achieved statistical significance on both co-primary endpoints vs. placebo:
 - Reduction in whole-blood metal-free PPIX from baseline (-41.4% vs. placebo, $p < 0.0001$)
 - Increase in average monthly total time in light without pain during month 6 (+12.2 hours vs. placebo, $p = 0.0010$)
- Bitopertin achieved statistical significance on all secondary endpoints vs. placebo, including:
 - Reduction in incidence rate of phototoxic reactions over the 6-month treatment period vs. placebo ($p < 0.0001$)
 - Increase in cumulative total time in light without pain over the 6-month treatment period vs. placebo ($p < 0.0001$)
 - Increase in change from baseline in average daily sunlight exposure time to prodrome vs. placebo ($p = 0.0077$, adults only)
- Bitopertin demonstrated additional quality of life benefits vs. placebo, including improved Patient Global Impression of Change (PGIC) score ($p < 0.0001$) and Patient Global Impression of Severity (PGIS) score ($p < 0.0001$)
- Bitopertin was generally well-tolerated. Consistent with prior studies, dizziness was the most commonly reported treatment emergent adverse event (TEAE) in the bitopertin group (50%) and was mild or moderate and generally transient. There were no TEAEs above Grade 3.

The APOLLO study adds to an extensive clinical data package supporting bitopertin's potential in EPP. Based on these results, Disc plans to resubmit a New Drug Application (NDA) to the U.S. FDA by the end of 2026, with an FDA decision anticipated by

mid-2027.

Management will host a corporate webcast this morning, Monday, October 19 at 8:00am EST to discuss the APOLLO topline results and next steps. Please register for the event on the Events and Presentations page of Disc's website (<https://ir.discmedicine.com/>).

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 planning to develop 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, the open-label extension HELIOS trial, and the 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 EPP

Erythropoietic protoporphyria (EPP), including X-linked Protoporphyria (XLP), is a rare, debilitating and potentially life-threatening disease caused by mutations that affect heme biosynthesis, resulting in the accumulation of a toxic, photoactive intermediate called protoporphyrin IX (PPIX). This causes severe reactions when patients are exposed to sunlight, characterized by excruciating pain, edema, burning sensations and potential blistering and disfigurement. PPIX also accumulates in the hepatobiliary system and can result in complications including gallstones, cholestasis, and liver damage in 20-30% of patients and in extreme cases liver failure. Current standard of care involves extreme measures to avoid sunlight, including restricting outdoor activities to nighttime, use of protective clothing and opaque shields, and pain management. This has a significant impact on the psychosocial development, quality of life, and daily activities of patients, particularly in young children and families. There is currently no cure for EPP and only one FDA-approved therapy, a surgically implanted synthetic hormone designed to stimulate melanin production called Scenesse® (afamelanotide).

About Disc Medicine

Disc Medicine 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 of bitopertin; anticipated engagement with regulators with respect to bitopertin, including the timing of an NDA resubmission and an FDA decision; and the potential therapeutic benefits of bitopertin as a treatment for EPP, if approved. 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; the content and timing of decisions made by the FDA and other regulatory authorities; 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.

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