



Disc Medicine Announces Grant of US Patent for Methods of Treating Erythropoietic Protoporphyrrias with Bitopertin

November 14, 2023

WATERTOWN, Mass., Nov. 14, 2023 (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 that the United States Patent and Trademark Office (USPTO) has issued patent No. 11,813,257 for methods of treating erythropoietic protoporphyrias (EPPs) with glycine transport inhibitors.

"We are pleased to have been issued this patent that further secures IP protection for bitopertin for the treatment of erythropoietic protoporphyria as we work to deliver a potentially transformative therapy to patients," said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. "This patent further highlights the innovative approach we are taking to treat EPP, as demonstrated by the data we shared in June, which we will update at ASH in December."

This patent covers uses of bitopertin, a glycine transport inhibitor, in treating erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP) with an anticipated expiration in 2041, before any available term extensions or adjustments. Disc intends to continue to prosecute additional patent applications to support use of bitopertin in treating hematologic disorders.

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. There are currently two ongoing Phase 2 clinical trials of bitopertin in patients with erythropoietic porphyria, including an open-label trial called BEACON and a randomized, double-blind placebo-controlled trial called AURORA.

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 Erythropoietic Protoporphyria (EPP) and X-linked Protoporphyria (XLP)

Erythropoietic protoporphyria (EPP) and X-linked Protoporphyria (XLP) are rare, debilitating and potentially life-threatening diseases 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 (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 its patent portfolio for bitopertin; its AURORA Phase 2 and BEACON Phase 2 clinical studies of bitopertin and the results thereof; projected timelines for the initiation and completion of its clinical trials, anticipated timing of release of data, and other clinical activities; and Disc's business plans and objectives. 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 patent portfolio for bitopertin for the treatment of EPP; Disc's ability to further enhance patent protection for bitopertin in treating disorders of heme biosynthesis; the nature, strategy and focus of Disc; Disc's plans to research, develop and commercialize its current and future product candidates; that the issuance of a patent for Disc's methods of treating EPPs may not necessarily be predictive of an innovative approach to treat EPP; the timing of the availability of data from Disc's clinical trials; the timing and anticipated results of Disc's preclinical studies and clinical trials and the risk that the results of Disc's 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 other risks and uncertainties described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022, Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023, and other documents filed by Disc from time to time with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Disc's subsequent filings with the SEC. 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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