Disc Medicine Receives FDA Fast Track Designation for MWTX-003 for the Treatment of Polycythemia Vera

September 20, 2023

WATERTOWN, Mass., Sept. 20, 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 Food and Drug Administration (FDA) has granted Fast Track Designation to MWTX-003 for the treatment of patients with polycythemia vera (PV).

"We are delighted to have received Fast Track designation for MWTX-003, which highlights the unmet need for PV patients and the potential of MWTX-003 in a disease where there are few treatment options," said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. "We believe MWTX-003 is uniquely positioned to address the needs of PV patients and are excited to initiate a Phase 1 trial in the coming months."

Fast Track is a process designed by the FDA to facilitate the development and expedite the review of investigational drugs intended to treat serious conditions and for which nonclinical or clinical data demonstrate the potential to address unmet medical need. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan. Therapeutic candidates with Fast Track designation may also be eligible for priority review and accelerated approval if supported by clinical data.

About MWTX-003
MWTX-003, also known as DISC-3405, is an investigational, anti-TMPRSS6 (Transmembrane Serine Protease 6, also known as Matriptase-2) monoclonal antibody designed to increase hepcidin production and suppress serum iron, that Disc in-licensed from Mabwell Therapeutics in January 2023. Preclinical studies of MWTX-003 have demonstrated an increase in hepcidin production and suppression of serum iron levels in animal models of beta-thalassemia and polycythemia vera. The IND was accepted in November 2022 and Disc plans to initiate a Phase 1 study of MWTX-003 in healthy volunteers during the second half of 2023. Disc plans to develop MWTX-003 initially as a treatment for polycythemia vera as well as other hematologic conditions.

MWTX-003 is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide.

About Polycythemia Vera (PV)

Polycythemia vera (PV) is a chronic and rare myeloproliferative neoplasm characterized by the abnormal proliferation of red blood cells. PV affects approximately 150,000 patients in the U.S. and has a similar prevalence in Europe. The overproduction of red blood cells alters the viscosity of blood, causing it to thicken and placing patients at an elevated risk of cardiovascular and thromboembolic events, such as heart attack and stroke. Patients also experience complications such as enlarged spleen and symptoms of their disease such as fatigue, pruritis, difficulty concentrating and others. Current therapy involves phlebotomy to physically remove blood and iron to limit erythropoiesis or treatment with cytoreductive agents, with the goal of reducing red blood cell count and managing symptoms.

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 AURORA Phase 2 and BEACON Phase 2 clinical studies of bitopertin, and its Phase 1b/2 study of bitopertin in Diamond-Blackfan Anemia, its Phase 1b/2 clinical study of DISC-0974 in NDD-CKD patients with anemia, its anticipated Phase 1 study of MWTX-003 and potential development of MWTX-003 as a treatment for polycythemia vera and other indications, projected timelines for the initiation and completion of its clinical trials, anticipated timing of release of data, and other clinical activities; Disc's business plans and objectives; and Disc's beliefs about operating expenses and that it will have capital to fund Disc well into 2026. 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 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.

Media Contact

Peg Rusconi
Verge Scientific Communications
prusconi@vergescientific.com

Investor Relations Contact

Christina Tartaglia
Stern Investor Relations
christina.tartaglia@sternir.com