Disc Medicine Initiates a Phase 1 Study of DISC-3405 (anti-TMPRSS6 mAb) in Healthy Volunteers

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WATERTOWN, Mass., Oct. 03, 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 the initiation of a Phase 1 study of DISC-3405 (formerly MWTX-003) in healthy volunteers. DISC-3405 is a monoclonal antibody designed to target TMPRSS6 (Transmembrane Serine Protease 6, also known as Matriptase-2) to increase hepcidin and decrease iron.

“The initiation of this trial marks the third program that Disc has brought into the clinic and strengthens our position as leaders in the field of hepcidin biology and iron homeostasis. We believe DISC-3405 has potential across a broad range of diseases where restricting iron may have therapeutic benefit, such as polycythemia vera, iron overload conditions, and other diseases. We look forward to pursuing those indications upon the completion of this trial,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “This milestone comes at an exciting time for us, as we plan to share data updates from ongoing clinical studies of our other two programs, bitopertin and DISC-0974, later this year.”

The study will be a randomized, double-blind, placebo-controlled, single- and multiple-ascending dose Phase 1 trial in healthy volunteers and will evaluate safety, tolerability, pharmacokinetics, and measures of pharmacodynamic activity, including markers of iron homeostasis and erythropoiesis. The single-ascending dose portion of the study is planned to enroll four cohorts at increasing dose levels, starting with intravenous administration with a plan to move to subcutaneous administration later in the study. The multiple-ascending dose portion is planned to enroll two cohorts, each receiving subcutaneous injections of DISC-3405. Following completion of this study, Disc plans to initiate a trial in polycythemia vera, for which DISC-3405 has received Fast Track Designation.

About DISC-3405 (previously MWTX-003)

DISC-3405, formerly known as MWTX-003, 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 DISC-3405 have demonstrated an increase in hepcidin production and suppression of serum iron levels in animal models of beta-thalassemia and polycythemia vera. Disc plans to develop DISC-3405 initially as a treatment for polycythemia vera as well as other iron-overload conditions.

DISC-3405 is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide.

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 Phase 1 study of DISC-3405 and potential development of DISC-3405 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.

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