Disc Medicine Receives FDA Fast Track Designation for DISC-0974 for the Treatment of Anemia in Non-Dialysis Dependent Chronic Kidney Disease

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WATERTOWN, Mass., Feb. 20, 2024 (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 DISC-0974 for the treatment of patients with non-dialysis dependent chronic kidney disease (NDD-CKD) and anemia.

“Receiving Fast Track designation highlights the unmet need for the millions of NDD-CKD patients with anemia, as well as the potential of DISC-0974 to address this need,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “We believe DISC-0974 could be a transformative therapy for these patients and are excited to share additional results from our ongoing Phase 1b/2 study in NDD-CKD patients with anemia this year.”

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 DISC-0974

DISC-0974 is an investigational monoclonal antibody (mAb) targeting a BMP-signaling co-receptor called hemojuvelin (HJV) and is designed to suppress hepcidin production and increase serum iron levels in patients suffering from anemia of inflammation. DISC-0974 was in-licensed by Disc from AbbVie in 2019. Anemia of inflammation arises from abnormally elevated hepcidin and affects millions of patients in the US across numerous diseases such as chronic kidney disease, myelofibrosis, cancer, autoimmune diseases, and other conditions with an inflammatory component. Disc has established clinical proof-of-mechanism of DISC-0974 in a Phase 1 trial of healthy volunteers and has ongoing clinical studies of DISC-0974 in patients with myelofibrosis and anemia and also in patients with NDD-CKD and anemia.

DISC-0974 is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide.

About Anemia of Chronic Kidney Disease (CKD)

Chronic kidney disease (CKD) is a global, widespread disease characterized by progressive loss of kidney function and may lead to end-stage renal disease (ESRD) or kidney failure. CKD affects over 37 million patients in the United States and an estimated 700 million patients worldwide. Anemia is a serious and frequent complication of CKD, as patients are unable to produce sufficient red blood cells and hemoglobin. It affects approximately 5-6 million patients in the U.S. alone, may result in fatigue, shortness of breath, and reduced physical and cognitive function, and can be associated with a higher risk of mortality, hospitalization and other complications. Elevated hepcidin is a primary cause of anemia in CKD patients and prevents erythropoiesis by depriving developing red blood cells of iron. Hepcidin accumulates at high levels in CKD patients because its production is stimulated by inflammation and its clearance is reduced as a consequence of impaired renal function. The majority of CKD patients do not receive any treatment for their anemia due to the complexity of outpatient administration and potential safety concerns related to the current treatments. In severe cases, patients may receive blood transfusions, but transfusions require significant healthcare utilization, incur safety risks and increase the potential for immune sensitization which precludes eligibility for kidney transplantation.

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 Phase 1b/2 clinical study of DISC-0974 in NDD-CKD patients with anemia, 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, June 30, 2023, and September 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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