Disc Medicine Presents Positive Data from SAD Cohorts of a Phase 1b Trial in Patients with Chronic Kidney Disease (CKD) and Anemia at the 2024 American Society of Nephrology (ASN) Kidney Week

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WATERTOWN, Mass., Oct. 25, 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 presented positive additional data from an ongoing Phase 1b study of DISC-0974 in patients with non-dialysis-dependent chronic kidney disease (NDD-CKD) and anemia, including results from the 40 mg and 60 mg single ascending dose (SAD) cohorts. The data presented at the 2024 American Society of Nephrology (ASN) Kidney Week in San Diego, CA demonstrated that a single dose of DISC-0974 results in sustained suppression of hepcidin and mobilization of iron, and increased erythropoiesis and levels of hemoglobin in NDD-CKD patients with anemia.

“We are pleased to present these updated results, which provide the first clinical evidence in CKD anemia that reducing hepcidin through hemojuvelin translates into increased erythropoiesis and hemoglobin. Importantly, we were able to observe activity following only a single dose of DISC-0974, which will enable us to efficiently explore dose regimens in the multiple-dose portion of the Phase 1b study,” said John Quisel, JD, PhD, President and Chief Executive Officer of Disc Medicine. “We have now shown that DISC-0974 can improve anemia in the settings of both myelofibrosis and chronic kidney disease. This speaks to the much broader potential for DISC-0974 to address anemia caused by a range of inflammatory and chronic diseases, each of which are associated with elevated hepcidin, and we look forward to providing our plans to access these indications.”

In the SAD portion of this study, participants with Stage 2-5 NDD-CKD were given a single dose of placebo (n=7) or DISC-0974 subcutaneously (SC) at 28 mg (n=9), 40 mg (n=6), or 60 mg (n=6). Dose escalation is ongoing in the SAD. This interim data set demonstrated:

- Substantial, durable, dose-dependent reduction in hepcidin from baseline compared to placebo across dose levels, with median reduction greater than 75% from baseline at highest dose level
- Meaningful and sustained increase in transferrin saturation from baseline compared to placebo across dose levels, with median increase up to 3x from baseline at highest dose level
- Early and sustained increase in mean reticulocyte hemoglobin from baseline across all dose groups through Day 22 and beyond
    - Maximal mean values through Day 22 of +1.14 pg at 28 mg, +1.49 pg at 40 mg, and +1.53 pg at 60 mg, compared with +0.21 pg on placebo
- Increase in mean hemoglobin from baseline across dose groups over the study period
    - Change greater than placebo: +0.35 g/dL at 28 mg, +0.54 g/dL at 40 mg, and +0.55 g/dL at 60 mg
- Mean maximal increase in hemoglobin of +0.8 g/dL at 40 mg and +0.7 g/dL at 60 mg compared with +0.2 g/dL on placebo
    - Maximal observed individual increase in hemoglobin up to +0.95 g/dL at 28 mg, +1.5 g/dL at 40 mg, and +1.8 g/dL at 60 mg
- DISC-0974 demonstrated acceptable safety and tolerability at all evaluated dose levels
    - The majority of adverse events were deemed not related to DISC-0974 and all adverse events assessed as treatment-related were Grade 1 or 2

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

About Anemia of Chronic Kidney Disease

Chronic kidney disease is a global, widespread disease characterized by progressive loss of kidney function and may lead to end-stage renal disease 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 to 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 due to impaired renal function. Most 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 use may lead to increased administrative burden, safety risks and the potential for immune sensitization which precludes eligibility for kidney transplantation.

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 its phase 1b clinical study of DISC-0974 in NDD-CKD patients with anemia, including the multiple dose portion of this clinical study and the results thereof; and the potential for expansion opportunities in anemia associated with other inflammatory diseases. 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; and the other risks and uncertainties described in Disc's filings with the Securities and Exchange Commission, including in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023, 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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