



## **Disc Medicine Receives FDA Orphan Drug Designation for Bitopertin for the Treatment of Erythropoietic Protoporphyria**

December 27, 2022

WATERTOWN, Mass. (December 27, 2022) –Disc Medicine, Inc. ("Disc"), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases, announced today that the U.S. Food and Drug Administration ("FDA") granted Orphan Drug Designation to bitopertin for the treatment of erythropoietic protoporphyria ("EPP"). Bitopertin is an investigational oral, selective inhibitor of glycine transporter 1 ("GlyT1") designed to modulate heme biosynthesis, and has been shown in preclinical studies to reduce accumulation of protoporphyrin IX ("PPIX"), the toxic metabolite that causes disease pathology in EPP patients. It is currently being studied in two ongoing Phase 2 studies in EPP, AURORA (NCT05308472) and BEACON (ACTRN12622000799752).

"Receiving orphan drug designation for bitopertin is incredibly encouraging and validates our commitment to bring a potential new treatment to EPP patients," said John Quisel, J.D., Ph.D., Chief Executive Officer and President of Disc. "We are eagerly awaiting the results of our ongoing Phase 2 trials and look forward to collaborating with the FDA to progress bitopertin through clinical development."

FDA Orphan Drug Designation may be granted to investigational drugs or biological products which show promise in treating rare medical diseases or conditions that affect fewer than 200,000 people in the United States. By receiving Orphan Drug Designation, bitopertin can benefit from certain development incentives and seven years of market exclusivity, subject to regulatory approval.

### **About EPP**

EPP is a rare, debilitating and potentially life-threatening diseases caused by mutations that affect heme biosynthesis, resulting in the accumulation of a toxic, photoactive intermediate, 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 Bitopertin**

Bitopertin is a clinical-stage, orally administered inhibitor of 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. The safety profile and effects of bitopertin on heme biosynthesis were previously established in a comprehensive clinical program comprising over 4,000 individuals across multiple clinical studies. Disc is planning to develop bitopertin as a potential treatment for a range of hematologic diseases beginning with EPP and X-linked protoporphyria ("XLP"). In preclinical models of EPP and XLP, bitopertin was shown to significantly decrease PPIX, a toxic intermediate of heme biosynthesis which is the underlying cause of the disease.

Bitopertin is an experimental 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 Disc Medicine, Inc.**

Disc is a clinical-stage biopharmaceutical company that is dedicated to transforming the lives of patients with hematologic disorders. We are building a portfolio of innovative, potential first-in-class therapeutic candidates that affect fundamental pathways of red blood cell biology. We are committed to developing treatments that empower and bring hope to the many patients who suffer from hematologic diseases. In August 2022, Disc announced it entered into a definitive merger agreement with Gemini Therapeutics, Inc. (NASDAQ:GMTX) ("Gemini"). For more information, please visit [www.discmedicine.com](http://www.discmedicine.com).

### **Disc Cautionary Statement Regarding Forward-Looking Statements**

Certain statements in this press release may constitute "forward-looking statements" for purposes of the federal securities laws concerning the proposed transaction between Disc and Gemini including whether and when the proposed transaction will be consummated; statements about the structure, timing and completion of the proposed transaction; and other matters, including Disc's expectations with respect to its AURORA and BEACON clinical trials and Phase 1b/2a clinical study of DISC-0974 in myelofibrosis and anemia, its plans to initiate a Phase 2 study of DISC-0974 in chronic kidney disease, and other statements that are not historical in nature. These forward-looking statements include express or implied statements relating to Disc's management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Disc, Gemini or the proposed transaction will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Disc's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the conditions to the closing of the transaction are not satisfied, including the failure to obtain stockholder approval for the transaction; the risk that the concurrent financing is not

completed in a timely manner or at all; uncertainties as to the timing of the consummation of the transaction and the ability of each of Gemini and Disc to consummate the transaction, including the concurrent financing; risks related to Gemini's continued listing on the Nasdaq Stock Market until closing of the proposed transaction; risks related to Gemini's and Disc's ability to correctly estimate their respective operating expenses and expenses associated with the transaction, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; the effect of the announcement or pendency of the merger on Gemini's or Disc's business relationships, operating results and business generally; costs related to the merger; the outcome of any legal proceedings that may be instituted against Gemini, Disc or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby; the ability of Gemini or Disc to protect their respective intellectual property rights; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of the proxy statement/prospectus included in the registration statement on Form S-4 (the "Initial Registration Statement"), which was initially filed on September 2, 2022, as amended by Amendment No. 1 to the Initial Registration Statement filed with the SEC on October 7, 2022, Amendment No. 2 to the Initial Registration Statement filed with the SEC on November 3, 2022, Amendment No. 3 to the Initial Registration Statement filed with the SEC on November 23, 2022 and Amendment No. 4 to the Initial Registration Statement filed with the SEC on December 1, 2022 (together with the Initial Registration Statement, the "Registration Statement") and declared effective on December 2, 2022, in connection with the transaction and other documents filed by Gemini from time to time with the SEC. Should one or more of these risks or uncertainties materialize, or should any of Disc's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the ongoing COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Disc's forward-looking statements only speak as of the date they are made, and Gemini and Disc do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

#### **No Offer or Solicitation**

In connection with the proposed transaction between Gemini and Disc, Gemini filed with the SEC a registration statement on Form S-4, as amended, containing a definitive proxy statement/prospectus of Gemini. The registration statement was declared effective by the SEC on December 2, 2022, and the special meeting of Gemini stockholders is scheduled to be held on December 28, 2022. GEMINI URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT GEMINI, DISC, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and shareholders are able to obtain free copies of the definitive proxy statement/prospectus and other documents filed by Gemini with the SEC through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). In addition, investors and shareholders should note that Gemini communicates with investors and the public using its website ([www.geminitherapeutics.com](http://www.geminitherapeutics.com)) and the investor relations website (<https://investors.geminitherapeutics.com/>) where anyone is able to obtain free copies of the proxy statement/prospectus and other documents filed by Gemini with the SEC and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials before making any voting or investment decision with respect to the proposed transaction.

#### **Additional Information and Where to Find It**

In connection with the proposed transaction between Gemini and Disc, Gemini filed with the SEC a registration statement on Form S-4, as amended, containing a definitive proxy statement/prospectus of Gemini. The registration statement was declared effective by the SEC on December 2, 2022, and the special meeting of Gemini stockholders is scheduled to be held on December 28, 2022. GEMINI URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT GEMINI, DISC, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and shareholders are able to obtain free copies of the definitive proxy statement/prospectus and other documents filed by Gemini with the SEC through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). In addition, investors and shareholders should note that Gemini communicates with investors and the public using its website ([www.geminitherapeutics.com](http://www.geminitherapeutics.com)) and the investor relations website (<https://investors.geminitherapeutics.com/>) where anyone is able to obtain free copies of the proxy statement/prospectus and other documents filed by Gemini with the SEC and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials before making any voting or investment decision with respect to the proposed transaction.

#### **Participants in the Solicitation**

Gemini, Disc and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Gemini's directors and executive officers is included in Gemini's most recent Annual Report on Form 10-K, including any information incorporated therein by reference as filed with the SEC, and the definitive proxy/prospectus filed by Gemini with the SEC on December 2, 2022, and any amendments thereto as filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

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