# Disc Medicine Initiates AURORA, a Phase 2 Clinical Study of Bitopertin in Adults with Erythropoietic Protoporphyria (EPP)

October 31, 2022

*AURORA study designed to evaluate bitopertin as a potential disease-modifying treatment for adults with EPP in the United States*

*Aurora study designed to assess changes in protoporphyrin IX levels, safety, tolerability, photosensitivity and other measures in a double-blind, placebo-controlled setting; top-line data expected in 2023*

WATERTOWN, Mass. (October 31, 2022) – Disc Medicine, a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from serious hematologic diseases, announced today the initiation of AURORA, a Phase 2 clinical study of bitopertin in adults with EPP. Bitopertin is an 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. Bitopertin is also currently being studied in BEACON, an open-label Phase 2 clinical study in patients with EPP and X-linked protoporphyria (XLP), which was announced in August 2022 and is being conducted in Australia.

“We are delighted to initiate AURORA, the first US-based study of bitopertin in patients with EPP. We are conducting the AURORA study to enable us to evaluate the effects of bitopertin on PPIX levels, photosensitivity, pain and other key measures in a rigorous, blinded trial,” said John Quisel, JD, PhD, Chief Executive Officer at Disc Medicine. “We have designed AURORA and BEACON to provide us with a robust assessment of bitopertin’s potential as a disease-modifying therapy for EPP.”

The AURORA Phase 2 study is a randomized, double-blind, placebo-controlled, parallel dosing clinical trial designed to evaluate the safety, tolerability, and efficacy of bitopertin in adults with EPP. It is expected to enroll approximately 75 patients at sites throughout the United States. Patients will receive orally-administered bitopertin for 120 days at doses of either 20 mg once-daily or 60 mg once-daily. Upon completion of the 120-day treatment period, patients may roll over to the open-label extension portion of the trial. The study is designed to measure changes in levels of metal-free PPIX, as well as measures of photosensitivity, daylight tolerance, pain, safety, and tolerability.

“There is a significant unmet need for disease-modifying therapies for EPP that address the underlying pathophysiology of the condition. Patients with EPP experience debilitating painful reactions, as well as potentially severe hepatobiliary effects, and the measures they must take to avoid the sun can have a strong, negative impact on their quality of life,” said Cynthia Levy, MD, FAASLD, AGAF, University of Miami Miller School of Medicine. “We are very excited about the potential for bitopertin to address the underlying protoporphyrin accumulation that causes EPP symptoms and hepatopathy, and we look forward to the results.”

**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 Medicine is planning to develop bitopertin as a potential treatment for a range of hematologic diseases beginning with EPP and 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 Erythropoietic Protoporphyria (EPP) and X-linked Protoporphyria (XLP)**

EPP and XLP are rare, debilitating and potentially life-threatening diseases caused by mutations that affect heme biosynthesis, resulting in the accumulation of a toxic, photoactive intermediate called protoporphyrin IX (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 Disc Medicine**

Disc Medicine 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, potentially 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). For more information, please visit www.discmedicine.com.

**Disc Medicine 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 Disc's expectations with respect to its AURORA clinical study and other matters, including the proposed transaction between Disc and Gemini Therapeutics, Inc. (Gemini) announced in August 2022. 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 which was initially filed with the SEC in September 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**

This press release is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

**Important Additional Information Will be Filed with the SEC**

In connection with the proposed transaction between Gemini and Disc, Gemini intends to file relevant materials with the SEC, including a registration statement on Form S-4 that contains a proxy statement/prospectus of Gemini and information statement of Disc, which was initially filed on September 2, 2022. DISC URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT GEMINI, DISC, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and shareholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemini with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In

addition, investors and shareholders should note that Gemini communicates with investors and the public using its website (www.geminitherapeutics.com), the investor relations website (https://investors.geminitherapeutics.com/) where anyone will be able to obtain free copies of the proxy statement/prospectus/information statement 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 when they become available before making any voting or investment decision with respect to the proposed transaction.

**Participants in the Solicitation**

Gemini and its 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 registration statement on Form S-4 initially filed with the SEC on September 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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