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Journey Medical Corporation Announces Positive Comparative Pharmacokinetic (PK) Data for DFD-29

Phase 3, registrational studies remain on track for first half of 2023 topline data readout

SCOTTSDALE, Ariz., Dec. 20, 2022 (GLOBE NEWSWIRE) -- Journey Medical Corporation (NASDAQ: DERM) ("Journey Medical"), a commercial-stage biopharmaceutical company focused on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions, today announced positive PK comparability data of DFD-29 and key updates on the progress of its pivotal, Phase 3 clinical study of DFD-29 for the treatment of papulopustular rosacea in collaboration with Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's").

The PK study was designed as a single-center, randomized, open-label, single-dose, three-treatment, crossover, comparative bioavailability study of Journey Medical's DFD-29 (Minocycline Modified Release Capsules 40 mg) versus SOLODYN® (Minocycline Modified Release Tablets 105 mg). A total of 24 healthy adult volunteers were enrolled and examined for up to 30 days. The primary objectives of the study were to assess: 1) the comparative bioavailability of DFD-29 (Minocycline MR Capsules 40 mg) with SOLODYN® (Minocycline MR Tablets 105 mg) following a single oral dose administration under fasting conditions in healthy adult human subjects; and 2) the effect of food on the bioavailability of DFD-29 (Minocycline MR Capsules 40 mg). The secondary objective of the study was to evaluate and compare the safety and tolerability profiles of each study treatment. The study successfully demonstrated that the systemic exposure of DFD-29 (40 mg) was significantly lower than that of SOLODYN (105 mg). Additionally, the study showed that food did not have a significant effect on the pharmacokinetics of DFD-29.

Claude Maraoui, Co-Founder, President and Chief Executive Officer of Journey Medical, stated, "We are pleased to continue advancing the DFD-29 clinical program as part of our collaboration with Dr. Reddy's. The PK data indicate the safety of DFD-29 is on par with SOLODYN. To date, the enrollment of our pivotal, Phase 3 program has reached 96 percent. We look forward to providing further updates on the DFD-29 program including potential topline data from the Phase 3 studies, anticipated in the first half of 2023. Journey Medical also plans to file a New Drug Application ("NDA") in the second half of 2023. We hope to show the potential of DFD-29 as an effective treatment option for the millions of patients

worldwide who suffer with rosacea."

Additional information on this DFD-29 study can be found on ClinicalTrials.gov using the identifier: NCT05452785.

About Journey Medical Corporation

Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical") is focused on identifying, acquiring, developing and strategically commercializing innovative, differentiated dermatology products through its efficient sales and marketing model. The company currently markets eight products that help treat and heal common skin conditions. The Journey Medical team is comprised of industry experts with extensive experience commercializing some of the most successful prescription dermatology brands. Journey Medical is located in Scottsdale, Arizona and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). Journey Medical's common stock is registered under the Securities Exchange Act of 1934, as amended, and it files periodic reports with the U.S. Securities and Exchange Commission ("SEC"). For additional information about Journey Medical, visit www.journeymedicalcorp.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words "we", "us" and "our" may refer to Journey Medical. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. The words "anticipate," "believe," "estimate," "may," "expect," "will," "could," "project," "intend" and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials, including disruptions that may result from hostilities in Europe; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; potential recovery of funds lost from previously disclosed cyber security breaches; as well as other risks described in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 28, 2022, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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