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Journey Medical Corporation Announces First Patient Dosed in Phase 3 Clinical Trial Evaluating DFD-29 (Minocycline Modified Release Capsules 40 mg) for the Treatment of Rosacea

Published Phase 2 clinical data show DFD-29 had approximately double the efficacy compared to Doxycycline capsules 40 mg on reducing total inflammatory lesions and IGA treatment success

SCOTTSDALE, Ariz., March 17, 2022 (GLOBE NEWSWIRE) -- Journey Medical Corporation (NASDAQ: DERM) ("Journey Medical"), a commercial-stage pharmaceutical company that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions, today announced that the first patient has been dosed in a Phase 3 clinical trial to assess the safety, efficacy and tolerability of DFD-29 (Minocycline Modified Release Capsules 40 mg) for the treatment of papulopustular rosacea. The Phase 3 clinical trials are part of a collaboration with Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's") for the ongoing development and commercialization of the DFD-29 program.

Two multicenter, randomized, double-blind, parallel-group, active and placebo-controlled Phase 3 clinical trials will each enroll up to 320 adult patients with moderate to severe papulopustular rosacea ("PPR"). One trial is enrolling patients in the United States and the other is enrolling in the United States and Europe. The studies will be randomized in a 3:3:2 ratio to DFD-29 (Minocycline Hydrochloride Modified Release Capsules, 40 mg), Oracea[®] (Doxycycline capsules 40 mg) or placebo once daily for 16 weeks. The primary objective of the studies is to evaluate the safety, efficacy and tolerability of DFD-29 compared to placebo for the treatment of PPR. The secondary objective is to evaluate the safety, efficacy and tolerability of DFD-29 compared to Oracea[®] (Doxycycline capsules 40 mg).

Claude Maraoui, Co-Founder, President and Chief Executive Officer of Journey Medical, stated, "Reaching this milestone marks another important inflection point for Journey Medical. We began as a commercial-stage pharmaceutical company and have evolved into a fully-integrated pharmaceutical company with a research and development division that has the capability to expand available dermatologic treatment options. Research to date

demonstrates the potential of DFD-29 as a more effective treatment option that we hope to provide for the millions of patients worldwide that suffer with rosacea.”

Research published in [The Journal of Clinical and Aesthetic Dermatology](#) in December 2021 determined DFD-29 40 mg demonstrated significantly greater efficacy than Doxycycline 40 mg, placebo and DFD-29 20 mg for the treatment of PPR, at plasma concentrations predicted to be below the antimicrobial threshold. The research comprised of two studies, a single-center open-label, three-arm, Phase 1 pharmacokinetic study with 24 randomized healthy subjects aged 18 to 45 years that received 21 days of once-daily dosing with DFD-29 40 or 20mg, or Doxycycline 40mg and a multicenter Phase 2 clinical trial with 205 randomized patients with mild-to-severe PPR who received once-daily DFD-29 40 or 20 mg, Doxycycline 40 mg, or placebo for 16 weeks. DFD-29 demonstrated statistical significance compared to both placebo and doxycycline on both co-primary endpoints—proportion of subjects with Investigator’s Global Assessment (“IGA”) treatment success (grade 0 or 1 with at least a two grade reduction from baseline at week 16) and total inflammatory lesion count reduction from baseline to week 16. Most notably, DFD-29 had approximately double the efficacy compared to doxycycline on both co-primary endpoints.

About Rosacea

Rosacea is a chronic, relapsing, inflammatory skin condition that most commonly presents with symptoms such as deep facial redness, acne-like inflammatory lesions (papules and pustules) and spider veins (telangiectasia). Based on research in the [British Journal of Dermatology](#), it is estimated that 415 million people suffer with rosacea worldwide.¹ Rosacea is most frequently seen in adults between 30 and 50 years of age. Surveys conducted by [The National Rosacea Society](#) report more than 90 percent of rosacea patients said their condition had lowered their self-confidence and self-esteem, and 41 percent reported that it had caused them to avoid public contact or cancel social engagements. Among rosacea patients with severe symptoms, 88 percent said the disorder had adversely affected their professional interactions, and 51 percent said they had missed work because of their condition.

1. Gether L, Overgaard LK, Egeberg A, Thyssen JP. [Incidence and prevalence of rosacea: a systematic review and meta-analysis](#). *Br J Dermatol* 2018 Feb 25. doi: 10.1111/bjd.16481

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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 nine products that help treat and heal common skin conditions. The Journey Medical team is comprised of industry experts with extensive experience in developing and 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 is registered under the Securities Exchange Act of 1934, as amended, and 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. 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; as well as other risks described in our SEC filings. 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. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying mutatis mutandis to every other instance of such information appearing herein.

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