

January 10, 2023



## **Journey Medical Corporation Completes Enrollment in Phase 3 Clinical Trials Evaluating DFD-29 (Minocycline Modified Release Capsules 40 mg) for the Treatment of Papulopustular Rosacea**

**Topline data expected in the first half of 2023**

SCOTTSDALE, Ariz., Jan. 10, 2023 (GLOBE NEWSWIRE) -- Journey Medical Corporation (NASDAQ: DERM) ("Journey Medical"), a commercial-stage biopharmaceutical company that focuses on the development and commercialization of pharmaceutical products for the treatment of dermatological conditions, today announced that it has fully enrolled and randomized all of the patients in its Phase 3 clinical program to assess the safety, efficacy and tolerability of DFD-29 (Minocycline Modified Release Capsules 40 mg) for the treatment of papulopustular rosacea ("PPR"). The Phase 3 clinical trials are part of a collaboration with Dr. Reddy's Laboratories Ltd. for the ongoing development and commercialization of the DFD-29 program.

Claude Maraoui, Co-Founder, President and Chief Executive Officer of Journey Medical, stated, "We are thrilled to have completed enrollment in our two DFD-29 Phase 3 clinical trials and look forward to announcing topline data in the first half of 2023, with a New Drug Application ("NDA") filing subsequently expected in the second half of 2023. We are extremely grateful to the patients, physicians and their research teams participating in these clinical trials, as they are essential to the development of a new treatment option for the millions of patients worldwide who suffer with rosacea. Data from the Phase 2 multicenter clinical trial demonstrated that DFD-29 achieved nearly double the efficacy compared to doxycycline capsules 40 mg on reducing total inflammatory lesions and Investigator's Global Assessment ("IGA") treatment success, suggesting the potential of DFD-29 as a more effective treatment option for rosacea. After approval, we anticipate DFD-29 achieving peak annual net sales exceeding \$100 million."

The DFD-29 Phase 3 clinical program consists of two multicenter, randomized, double-blind, parallel-group, active-comparator and placebo-controlled clinical trials, MVOR-01 and MVOR-02 (Minocycline versus Oracea® in Rosacea), that are expected to support an NDA submission in the United States and potentially a Marketing Authorization Application in

Europe. The combined enrollment target of 640 total adult patients with moderate to severe PPR was achieved in the trials; one trial was enrolling patients in the United States, and the other was enrolling patients in both the United States and Europe. The MVOR-01 and MVOR-02 clinical trials are 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 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). To date, no major safety issues have been reported, and no drug-related serious adverse events have been observed.

Data published in [The Journal of Clinical and Aesthetic Dermatology](#) determined DFD-29 40 mg demonstrated significantly greater efficacy than doxycycline 40 mg, placebo and DFD-29 20 mg for the treatment of PPR in a Phase 2 clinical study. DFD-29 40 mg demonstrated statistical significance compared to both placebo and doxycycline 40 mg on both co-primary endpoints—proportion of subjects with 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.

Additional information on the DFD-29 Phase 3 clinical trial program can be found on ClinicalTrials.gov using the identifiers: [NCT05296629](#) and [NCT05343455](#).

### **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). According to [The National Rosacea Society](#), it is estimated that rosacea affects well over 16 million Americans and as many as 415 million worldwide. 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.

Oraycea® and Oracea® are registered trademarks of Galderma Holdings, S.A.

### **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 comprises industry experts with extensive experience in developing and commercializing some of dermatology’s most successful prescription 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](http://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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