Evelo Biosciences Announces Top-Line Results From its Phase 2 Clinical Study with EDP2939 in Moderate Psoriasis

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- Primary endpoint was not achieved –

- Company exploring strategic alternatives and partnering opportunities for EDP1815 and its SINTAX platform -

CAMBRIDGE, Mass., Oct. 17, 2023 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO) (“Evelo” or the “Company”), a clinical stage biotechnology company developing a novel platform of orally delivered inflammation-resolving medicines acting on the small intestinal axis (SINTAX), today announced top-line results from its Phase 2 clinical study with EDP2939 in moderate psoriasis. The study’s primary endpoint, the difference in the proportion of patients who achieved an outcome of a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI) score (a PASI-50 response) between EDP2939 and placebo after 16 weeks of daily treatment, was not achieved. The Company is continuing to gather and analyze the study data.

Simba Gill, Ph.D., Chief Executive Officer of Evelo, commented, “Whilst we are disappointed with the results of the Phase 2 study with EDP2939, we continue to believe in the value of our Small Intestinal Axis (SINTAX) platform and in our potential product, EDP1815. We previously reported positive efficacy and safety data in a Phase 2 study of mild to moderate psoriasis with EDP1815. We will cease development of EDP2939, given the results of this study, and are conducting a review of potential strategic alternatives, including seeking to partner EDP1815 and the SINTAX platform. I want to thank patients and investigators who participated in the study, and our team and shareholders for their support.”

In the EDP2939-101 Phase 2 study, the primary endpoint was the difference in the proportion of patients who reached at least PASI-50 reductions between EDP2939 and placebo after 16 weeks of daily treatment. A PASI-50 response was chosen as this is clinically meaningful for patients with moderate psoriasis and had been positive in the previous study with EDP1815. Although there was no statistically significant difference between the proportion of patients who achieved a PASI-50 response on EDP2939 compared to placebo, it was notable that such numeric proportion went from being inferior to placebo at week 16 (19.6% on EDP2939 vs 25% on placebo) to being superior at the week 20 follow-up visit (33.9% on EDP2939 vs 26.9% on placebo). Ongoing analysis of the secondary endpoints continues.

Overall safety data was consistent with what was previously reported in the Phase 1 portion of this study: EDP2939 was well-tolerated with adverse events (AEs) comparable to placebo. AEs classified as “gastrointestinal” were comparable between active and placebo groups, with no meaningful differences in rates of diarrhea, abdominal pain, nausea, or vomiting. There were no related serious adverse events (SAEs).

Based on these results, Evelo has initiated a process to explore strategic alternatives.

About Evelo Biosciences
Evelo Biosciences is a clinical stage biotechnology company developing a novel platform of orally delivered anti-inflammatory medicines acting on the small intestinal axis, SINTAX, with systemic therapeutic effects. The small intestine plays a central role in governing inflammation throughout the body. The Company’s product candidates are pharmaceutical preparations of single strains of microbes or their extracellular vesicles (EVs). Evelo’s vision is to create therapies that are effective, safe, well-tolerated, and affordable to improve the lives of the billions of people living with inflammatory diseases. If shown to be effective in inflammatory disease mediated by the Th1, Th2 or Th17 inflammatory pathways, these same investigational medicines could be effective in additional inflammatory diseases, such as psoriatic and other forms of arthritis, asthma, allergy, and inflammatory bowel disease.

For more information, please visit www.evelobio.com.

About the EDP2939-101 Trial
EDP2939-101 is a multi-center randomized, placebo-controlled, Phase 1/2 trial evaluating the safety, tolerability and clinical efficacy of EDP2939. Part A (Phase 1) of the trial is designed to evaluate safety and tolerability in human volunteers at multiple ascending doses. The primary endpoints of Part A are safety endpoints: AEs, SAEs, vital signs, safety laboratory tests, and ECGs. Part B (Phase 2) is designed to evaluate the efficacy of EDP2939 in patients with moderate plaque psoriasis at a dose of one capsule daily. The primary endpoint is the proportion of patients who achieve an outcome of a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI) score (a PASI-50 response) after 16 weeks of daily oral administration of EDP2939 or placebo. A follow-up assessment is done after 20 weeks (post 4 weeks from completion of dosing of EDP2939 or placebo). Secondary endpoints include several physician and patient-reported psoriasis outcomes, as well as further safety evaluation. The trial comprised approximately 106 patients randomized 1:1 to receive a single capsule of either EDP2939 or a matching placebo.

About the EDP1815-201 Trial
EDP1815-201 was a multicenter, randomized, double-blind, placebo-controlled, parallel-cohort, dose-ranging trial in adult patients with mild and moderate psoriasis. The study included a Part A (treatment phase) and Part B (extended follow-up phase, off-treatment). In Part A of the trial, 249 patients were randomized in a 1:1:1 ratio to one of three parallel cohorts: 1 capsule, 4 capsules or 10 capsules. They were then randomized in a 2:1 ratio to active or placebo prior to starting dosing. Trial medication was taken once daily for 16 weeks, and patients were followed for 4 weeks after treatment completion to week 20. In the trial, the PASI scores were assessed by both mean changes from baseline and responder rates. The primary endpoint was the mean percentage change in PASI between treatment and placebo. Secondary endpoints included the proportion of trial participants who achieved a PASI-50 response or greater. The 16-week primary endpoint gave probabilities that EDP1815 was superior to placebo ranging from 80% to 90% across the prespecified analyses and cohorts. 25% to 32% of patients across the three cohorts who were treated with EDP1815 achieved a PASI-50 at week 16 compared to 12% on placebo.

In Part B of the trial, patients were followed for up to 24 weeks after they had stopped receiving EDP1815 or placebo. During the post-treatment period, durable and deepening clinical responses were observed, with no flare or rebound of psoriasis. There were 83 patients who had received EDP1815 in Part A who entered Part B. Thirty of these 83 patients achieved a PASI-50 or greater reduction at the end of Part A. Eighteen of the 30 patients remained at PASI-50 or greater at the end of Part B. Ten of these 30 patients achieved a PASI-75 or greater at the end of Part A and 5 of them remained at PASI-75 or greater at the end of Part B.

Forward Looking Statements

This press release contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements concerning the expected timing and nature of further data from the Phase 2 study with EDP2939 in moderate psoriasis; our plans to conduct a review of strategic alternatives and possible outcomes; and the potential value of the Company's EDP1815 product and platform. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the results of our evaluation of strategic alternatives may or may not be successful; we have incurred significant losses, are not currently profitable and may never become profitable; our projected cash runway; our need for additional funding; our ability to meet our debt obligations (including restrictive and operational covenants and terms of refinanced debt); our ability to cure or satisfactorily resolve any default arising from our debt agreements; our limited operating history; our unproven approach to therapeutic intervention; our ability to address regulatory questions and the likelihood of regulatory filings and approvals; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our reliance on third parties and collaborators to expand our microbial library, conduct our clinical trials, manufacture our product candidates, and develop and commercialize our product candidates, if approved; our lack of experience in manufacturing, selling, marketing, and distributing our product candidates; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; risks associated with international operations; our ability to operate with a reduced workforce, to manage potential growth and to retain key personnel, particularly following a significant downsizing; the potential volatility of our common stock; our management and principal stockholders have the ability to control or significantly influence our business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; and securities class action litigation against us. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Results on Form 10-Q for the quarter ended June 30, 2023, and our other reports filed with the United States Securities and Exchange Commission, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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