

Evelo Biosciences Presents Late-Breaking Oral Abstract on Data from Phase 2 Trial of EDP1815 in Psoriasis at 2022 American Academy of Dermatology Annual Meeting

March 26, 2022

CAMBRIDGE, Mass., March 26, 2022 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing SINTAX™ medicines as a new modality of orally delivered treatments for inflammatory disease, today presented a late-breaking oral abstract on data from a Phase 2 trial of EDP1815 in psoriasis at the 2022 American Academy of Dermatology (AAD) Annual Meeting, being held March 25-29 in Boston, Massachusetts.

"We are proud to join the dermatology community at AAD to share the latest data from the clinical development of EDP1815 in psoriasis. The data being shared demonstrate the potential of Evelo's SINTAX platform, and support progression towards registration trials for EDP1815," said Douglas Maslin, M.Phil, M.B. B.Chir, Dermatology and Pharmacology Physician at Addenbrooke's Hospital and Clinical Lead, Late Stage Development of Evelo. "These data, combined with positive feedback from patients and physicians, as highlighted by our recent [KOL event](#), suggest the potential profile of EDP1815 as a safe, effective, oral, and well-tolerated therapy for psoriasis, which could address a significant unmet need for patients across all stages of disease."

Late-Breaking Oral Presentation at AAD 2022

- **A phase 2 study investigating the effect of EDP1815, an orally-delivered, anti-inflammatory, gut-restricted commensal microbe in the treatment of mild and moderate plaque psoriasis**, D. Maslin, Y. Mihaylov, D. Macaro, N. Carpenter, G. Mehraei, M. Bodmer, J. Zung, M. Plinio, D. McHale, B. Ehst
 - EDP1815-201 was a Phase 2 clinical trial evaluating EDP1815 versus placebo for the treatment of mild and moderate psoriasis, comprised of a Part A, where patients received either EDP1815 or placebo for 16 weeks, and a Part B, where patients were followed for up to 24 weeks after they had stopped receiving EDP1815 or placebo.
 - EDP1815 was well tolerated with safety data comparable to placebo: no drug-related serious adverse events, and no meaningful difference in infections or gastrointestinal events observed.
 - During the 16-week dosing period, the primary endpoint analysis demonstrated EDP1815 was superior to placebo with 80-90% probability across each cohort. Each cohort showed increased Psoriasis Area and Severity Index (PASI) score responses, as measured by the proportion of patients achieving at least a 50% improvement in PASI (PASI-50) from baseline at week 16: statistically significant ($p < 0.05$) over placebo in cohorts 1 and 2. A post-hoc analysis comparing PGA 0/1 response rate showed statistical significance with a rate of 20.2% compared to 9.1% in placebo ($p = 0.048$).
 - 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.
 - These results provide the first demonstration in a Phase 2 trial of the safety and efficacy of an orally-administered, gut-restricted SINTAX medicine, proving the ability to harness SINTAX to treat systemic inflammation, and paving the way for a new modality of anti-inflammatory medicines.

About EDP1815

EDP1815 is an investigational oral medicine being developed for the treatment of inflammatory diseases. It is a non-live pharmaceutical preparation of a strain of *Prevotella histicola*, selected for its potential to provide systemic pharmacological effects after oral administration with gut-restricted distribution. Being non-live, it has not been observed to colonize the gut or modify the microbiome. Preclinically, EDP1815 had anti-inflammatory effects in models that cover multiple pathways of inflammation, Th1, Th2, and Th17. Clinical results from multiple independent cohorts provide evidence supporting EDP1815's potential to address Th1, Th2 and Th17-mediated inflammation.

About EDP1815-201

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 achieve 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.

All patients had the option to enter Part B of the trial. The objective of Part B was to assess durability of treatment response and incidence of rebound (e.g., increase in PASI score to 125% of baseline value or above, or onset of new pustular erythrodermic psoriasis within 3 months of cessation of dosing) following cessation of dosing. Patients in Part B were assessed during follow-up visits at weeks 24 and 28. Only patients who had achieved a PASI-50 or greater at week 16 were also evaluated at week 40. Patients were not permitted to start other psoriasis treatments or trials during Part B.

About Psoriasis

Psoriasis is a common chronic immune-mediated inflammatory skin disease, affecting up to 3% of the population worldwide. The disease is driven by Th17-inflammation, which results in the formation of thick red plaques with scaling. Psoriatic lesions can appear anywhere on the body but are most often seen on the knees, elbows, scalp, and lumbar area. In addition to the skin lesions, there are systemic manifestations of the disease including arthritis and fatigue, and a strong association with depression and metabolic syndrome.

Patients with mild and moderate psoriasis are underserved by current treatments. Topical therapies do not control systemic inflammation, have low rates of compliance, and in the case of topical steroids are not recommended for long-term use. The majority of novel therapies, including injectable high-cost biologics, are only approved for patients with moderate and severe disease. Even in the severe patient population, the majority of eligible patients do not receive biologics, instead opting for topical therapies or oral systemic therapies, which are associated with tolerability issues and/or with monitoring requirements tied to safety concerns.

About Evelo Biosciences

Evelo Biosciences is a clinical stage biotechnology company developing orally delivered product candidates that are designed to act on the small intestinal axis, SINTAX™, with systemic therapeutic effects. SINTAX plays a central role in governing the immune, metabolic, and neurological systems. The Company's first product candidates are pharmaceutical preparations of single strains of microbes selected for their potential to offer defined pharmacological properties. Evelo's therapies have the potential to be effective, safe, and affordable medicines to improve the lives of people with a broad range of inflammatory diseases.

Evelo currently has three product candidates in development for inflammatory diseases: EDP1815, EDP1867, and EDP2939. Evelo is advancing additional product candidates in other disease areas.

For more information, please visit www.evelobio.com and engage with Evelo on [LinkedIn](#).

Forward Looking Statements

This press release contains forward-looking statements 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 development of EDP1815 and our other product candidates, and the promise and potential impact of our product candidates.

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 impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; our unproven approach to therapeutic intervention; 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 retain key personnel and to manage our growth; 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; and securities class action litigation against us.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and our other reports filed with the SEC, 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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