Evelo Biosciences Reports Positive EDP1815 Interim Clinical Data in Psoriasis Patients at Low Dose in Ongoing Phase 1b Trial

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-EDP1815 was Well Tolerated with No Overall Difference Reported from Placebo-
-Patients Dosed with EDP1815 Showed a Reduction in Mean Lesion Severity Score vs. Placebo-
-Reductions Observed in Cellular Histological and Blood Immune Cell Biomarkers Consistent with Clinical Response -
-Phase 2 Initiation Planned for Early 2020-
-First in Human Data Suggest that Oral Biologics that Act on Cells in the Small Intestine Modulate Systemic Inflammation-
-Management to Host Conference Call at 8:30 a.m. ET-

CAMBRIDGE, Mass., Aug. 06, 2019 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq: EVLO), a biotechnology company developing oral biologics that act on cells in the small intestine with systemic therapeutic effects, today announced positive interim clinical data from the first cohort of patients with mild to moderate psoriasis from its ongoing Phase 1b trial of EDP1815, its clinical candidate for the treatment of inflammatory diseases. EDP1815 was well tolerated with no overall difference reported from placebo.

12 patients with mild to moderate psoriasis were randomized 2:1 to receive daily, oral administration of 550mg (1x dose) of EDP1815, or placebo, for 28 days. The primary endpoint was safety and tolerability. Secondary and exploratory endpoints included lesion severity score (LSS), a measure of clinical activity, cellular histological biomarkers and blood immune cell biomarkers taken from biopsies and blood samples, respectively, at the start and end of the 28-day dosing period.

Patients dosed daily for 28 days with 550mg of the enteric capsule formulation of EDP1815 showed a statistically significant ($p<0.05$) reduction in mean LSS at 28 days of 2 points, compared to a mean increase of 0.25 points in patients who received placebo. Data from patients dosed with EDP1815 showed a reduction in LSS over the dosing period ranging from 0 to 67 percent. LSS, a secondary endpoint, is a component of the Psoriasis Area and Severity Index (PASI) score and measures redness, thickness, and scaling of an individual psoriatic lesion across the dosing period and is a sensitive clinical measure for patients with mild to moderate disease.

Analysis of the change over the dosing period of the basal epithelium mitotic count, a secondary endpoint and a cellular driver of psoriasis pathology, showed a mean reduction of 2.25 cells/mm^2 in patients who received EDP1815 compared to no change in patients receiving placebo. Lower basal epithelium mitotic counts indicate a reduction of psoriasis pathology.

In an analysis of blood immune cell cytokine production following stimulation with lipopolysaccharide, an exploratory endpoint, the EDP1815 dosed patient group showed a reduction in cytokine production indicative of a systemic anti-inflammatory response, compared to no reduction in the placebo group.

Evelo plans to advance EDP1815 into Phase 2 in early 2020. This trial will investigate daily dosing of EDP1815 in mild to moderate psoriasis patients over 24 weeks. Multiple doses and formulations of EDP1815 will be investigated.

"We believe these first-in-human data support our core scientific thesis that oral biologics that target cells in the small intestine can drive systemic immune effects," said Duncan McHale, M.B.B.S., Ph.D., chief medical officer of Evelo. "The results we have observed on the lesion severity score, a component of the PASI score, and biomarkers of disease at the low dose of EDP1815 over a short dosing duration support the potential of our platform to identify oral biologics that modulate the immune system. We look forward to advancing EDP1815 into Phase 2 in psoriasis in early 2020 and studying it in other inflammatory diseases."

About the EDP1815-101 Clinical Trial
EDP1815-101 is a double-blind placebo-controlled Phase 1b trial designed to evaluate the safety and tolerability of EDP1815 in approximately 108 healthy volunteers and patients with mild or moderate psoriasis or atopic dermatitis. Prospectively defined secondary and exploratory endpoints include the effect of EDP1815 on clinical measures of disease and a range of biomarkers. Enrollment is underway in a cohort of mild to moderate psoriasis patients to be dosed with 2.76g (5x dose) of the enteric capsule formulation. One further cohort of psoriasis patients and one cohort of atopic dermatitis patients are planned to be dosed with a new formulation of EDP1815.

Evelo expects to present data from this initial cohort at a future scientific conference or medical meeting.

About the EDP1815 Phase 2 Clinical Trial
Evelo plans to advance EDP1815 into Phase 2 in early 2020. This trial is designed to investigate daily dosing of EDP1815 in mild to moderate psoriasis. The primary endpoint of the trial is expected to be reduction in the PASI score over 24 weeks, with an interim analysis at 12 weeks. Multiple doses and formulations of EDP1815 will be investigated. Part A of the trial is designed to select the optimal formulation and will test the enteric capsule formulation and the new formulation of EDP1815 versus placebo in approximately 180 patients. Evelo expects to report interim data from Part A of the study and select the optimal formulation for Part B of the study in late 2020. Part B of the study will test multiple doses of the optimal formulation against placebo for 24 weeks in approximately 250 patients.

About EDP1815
EDP1815 is an investigational orally delivered monoclonal microbial being developed for the treatment of inflammatory diseases. EDP1815 is a strain of *Prevotella histicola*, selected for its specific pharmacology. In preclinical studies EDP1815 has shown potent immunomodulatory effects on human immune cells *in vitro* and *in vivo* anti-inflammatory activity on a range of tissues, including skin, joints, gut, and the CNS.

Conference Call
Evelo will host a conference call and webcast at 8:30 a.m. ET today to review these clinical data, as well as data reported today for EDP1066. To access the call please dial 866-795-3242 (domestic) and 409-937-8909 (international) and provide the passcode 6380636. A live webcast of the call, including an accompanying slide presentation, will be available on the Investors sections of the Evelo website at www.evelobio.com. The archived webcast will be available approximately two hours after the conference call and will be available for 30 days following the call.

About Evelo Biosciences
Evelo Biosciences, Inc. is a clinical stage biotechnology company developing oral biologics that act on cells in the small intestine with systemic therapeutic effects. These cells in the small intestine play a central role in governing the immune, metabolic and neurological systems. The company's first product candidates are monoclonal microbials, single strains of microbes selected for defined pharmacological properties. They have been observed in preclinical models to have systemic dose-dependent effects, modulating multiple clinically validated pathways. Evelo's therapies have the potential to be effective, safe and affordable medicines to improve the lives of people with chronic disease and cancer.

Evelo currently has three product candidates, EDP1066 and EDP1815 for the treatment of inflammatory diseases and EDP1503 for the treatment of cancer. Evelo is also advancing additional oral biologics through preclinical development in other disease areas.

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

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 our development plans and new formulations, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, the timing of and plans to initiate clinical studies of EDP1815, the timing and results of any clinical studies or readouts.

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: 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 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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