# Evelo Biosciences Reports Further Positive EDP1815 Interim Clinical Data in Patients with Psoriasis at High Dose in Phase 1b Trial

November 5, 2019

--EDP1815 was Well Tolerated with No Overall Difference Reported from Placebo--

--Reduction in Mean Lesion Severity Score (LSS) at 28 Days Consistent with Low Dose Cohort--

-- Dose Response Trends Observed in LSS and PASI at Day 42--

--Phase 2 Study Initiation Expected in Early 2020--

--Further Clinical Support for Validation of Evelo Platform--

-- Management to Host Conference Call at 8:30 a.m. EST--

CAMBRIDGE, Mass., Nov. 05, 2019 (GLOBE NEWSWIRE) -- Evelo Biosciences (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today announced positive interim clinical data in an ongoing Phase 1b trial in individuals with mild to moderate psoriasis treated with a high dose of EDP1815, its clinical candidate for the treatment of a range of inflammatory diseases.

Eighteen individuals with mild to moderate psoriasis were randomized 2:1 to receive a daily oral administration of 2.76g (5x or high dose) of EDP1815 or placebo for 28 days. The primary endpoint is safety and tolerability. Secondary and exploratory endpoints include lesion severity score (LSS), Psoriasis Area and Severity Index (PASI), both measures of clinical activity, as well as cellular histological biomarkers and blood immune cell biomarkers taken from biopsies and blood samples at the start and end of the dosing period, respectively. Safety and tolerability and secondary clinical endpoints are also measured at day 42, 2 weeks after completion of dosing.

EDP1815 continued to be well tolerated in this cohort, with no overall difference reported from placebo. At the end of the 28-day dosing period, the high dose cohort showed a mean reduction in LSS consistent with previously reported data from a low dose cohort.

Two weeks following the completion of the dosing period, at day 42, the high dose cohort showed continued reductions from baseline in both mean LSS and PASI, which may be indicative of a sustained clinical effect and dose response.

A summary of the LSS and PASI results are shown in the tables below.

**Mean (+/-SE) Percentage Change in LSS vs. Start of Dosing Period** (1)

| | n | At end of 28-day dosing period | At day 42 |
|---|---|---|---|
| Placebo (2) | 10 | 0.6% (9.0%) | -7.2% (6.2%) |
| EDP1815 (high dose) | 12 | -15.1% (6.4%) | -24.1% (7.1%) |
| EDP1815 (low dose) | 8 | -22.8% (9.9%) | -9.0% (12.7%) |

**Mean (+/-SE) Percentage Change in PASI vs. Start of Dosing Period** (1)

| | n | At end of 28-day dosing period | At day 42 |
|---|---|---|---|
| Placebo (2) | 10 | -1.0% (13.2%) | -3.3% (14.8%) |
| EDP1815 (high dose) | 12 | -16.0% (8.1%) | -20.7% (8.2%) |

Note:

(1) This study was not sufficiently powered to detect statistically significant differences in clinical effect between treatment groups.

(2) Represents the combination of placebo arms for the low dose (n=4) and high dose (n=6) cohorts.

A range of histological and molecular biomarkers were measured in the high dose cohort, with trends in line with the clinical effects of EDP1815 at the cohort level.

“We are extremely encouraged by the interim clinical data from our high dose cohort of EDP1815. In a small number of individuals and short treatment duration we have seen consistent results in this Phase 1 study and sustained and continued reductions in LSS and PASI at the high dose two weeks post treatment. This reinforces our belief in EDP1815’s potential for patients with mild to moderate psoriasis and potentially for a wider range of inflammatory diseases,” said Duncan McHale, M.B.B.S., Ph.D., chief medical officer of Evelo. “These interim results underpin the biology of the small intestinal axis, its importance on systemic physiology, and the potential of our platform to develop medicines which harness this effect.”

“There are multiple efficacious options for severe psoriasis, but there is a significant need for new therapies for patients living with mild to moderate disease. Many patients suffer from limited but severe lesions that have a profound impact on quality of life,” said Dr. Mark Lebwohl, M.D., Professor and Chairman of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine. “The interim data for EDP1815, which show continuing reductions in clinical measures of disease over a short duration and that EDP1815 has been well tolerated, are encouraging. I look forward to the Phase 2 data and understanding how these results translate to a larger patient population over a prolonged treatment period.”

Evelo plans to advance EDP1815 into Phase 2 in early 2020. This placebo-controlled trial will investigate daily dosing of EDP1815 in individuals with

mild to moderate psoriasis over 16 weeks, and the primary endpoint will be a reduction in PASI score. Part A of the trial is designed to select an optimal formulation and will test the high dose of the enteric capsule formulation versus the high dose of a new formulation of EDP1815 versus placebo in approximately 180 individuals. Evelo expects to perform an interim analysis, and to report initial data from Part A of the trial, in late 2020, which will enable the selection of the optimal formulation and potential initiation of Part B. Part B is designed to test three doses of the optimal formulation determined in Part A against placebo in approximately 250 individuals.

**Lesion Severity Score (LSS)**
LSS, a secondary endpoint, is a component of the Psoriasis Area and Severity Index (PASI) score. It is a 12-pont scale which measures redness, thickness, and scaling of an individual psoriatic lesion and is a sensitive clinical measure for patients with mild to moderate disease.

**Psoriasis Area and Severity Index (PASI)**
PASI, a secondary endpoint, is a quantitative rating score for measuring the severity of psoriatic lesions based on area coverage and plaque appearance. PASI combines this assessment into a single score in the range of 0 (no disease) to 72 (maximal disease). The body is divided into four sections (head, arms, trunk, and legs). The average lesion severity score and area affected by lesions is assessed for each of these areas individually, and then the four scores are weighted and combined into a final PASI score.

**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 healthy volunteers and individuals 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. Evelo expects to report additional data from this study in a cohort of individuals with atopic dermatitis to be dosed with a new formulation of EDP1815 in Q2 2020. Based on the results today and the planned Phase 2 psoriasis study, Evelo will not enroll any further cohorts of individuals with psoriasis in this ongoing Phase 1b trial.

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

**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. EST today to review these clinical data. To access the call please dial 866-795-3242 (domestic) or 409-937-8909 (international) and refer to conference ID 7788384. A live webcast of the event will also be available under “News and Events” in the Investors section of Evelo's website at http://ir.evelobio.com. The archived webcast will be available on Evelo's website approximately two hours after the completion of the event 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 product candidates have the potential to be effective, safe and affordable medicines to improve the lives of people with chronic diseases 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, 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, and 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 June 30, 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.*

**Contact**

Evelo Biosciences
Jessica Cotrone, 978-760-5622
jcotrone@evelobio.com

Source: Evelo Biosciences, Inc.