Evelo Biosciences Reports New Positive Confirmatory Data from Phase 1b Trial of EDP1815 in Atopic Dermatitis

January 20, 2021

–EDP1815 was well tolerated, and showed clinically meaningful and consistent changes in all measured physician-reported outcomes –

–Improvements in patient-reported outcomes in DLQI and POEM, including itch–
–EASI50 benchmark reached in 44% of patients treated with EDP1815 compared to 0% in placebo group at day 70–
–Phase 2 atopic dermatitis trial initiation in 3Q 2021–

–Management to host conference call at 8:30 a.m. ET today with Dr. Benjamin Ehst–

CAMBRIDGE, Mass., Jan. 20, 2021 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered medicines, today announced new positive confirmatory data following completion of the mild and moderate atopic dermatitis cohort in its Phase 1b clinical trial. The Company previously reported interim data in 23 evaluable patients. These new results now include patient-reported outcomes, as well as all of the physician-reported outcomes for all 24 patients in the cohort. The primary endpoint of the Phase 1b trial was safety and tolerability. EDP1815 was well tolerated in this study with no treatment-related adverse events of moderate or severe intensity, and no serious adverse events.

Treatment with EDP1815 resulted in clinically meaningful improvement in the Dermatology Life Quality Index (DLQI) and Patient-Oriented Eczema Measure (POEM). These patient-reported outcomes capture the important impact of the disease on patients, including the domains of itch and sleep, both of which saw improvements in patients receiving EDP1815 on the study. All five measures of itch within the Pruritus-Numerical Rating Scale (Pruritus-NRS), SCORing Atopic Dermatitis (SCORAD), POEM, and DLQI showed greater improvements in the treated group at day 56 compared with placebo.

The full results also reinforce the positive interim data released on December 9, 2020. Additional physician- reported outcomes of Investigator's Global Assessment (IGA) and SCORAD were consistent with the previously reported Eczema Area and Severity Index (EASI) and IGA times Body Surface Area (IGAxBSA) measures. Table 1 shows the treatment difference between patients receiving EDP1815 and placebo as measured by percentage change of these well-established efficacy endpoints at day 56.

Table 1

Clinical Measure	**Treatment Difference between EDP1815 and Placebo Percentage Change at Day 56***
EASI	52% (p=0.062)
IGA*BSA	65% (p=0.022)
SCORAD	55% (p=0.043)

*Least Squares Mean Percentage Change From Baseline

The data showed consistent improvements in percentage change from baseline compared to placebo for all three clinical scores: EASI, IGA*BSA, and SCORAD. In addition, 7 out of 16 (44%) patients treated with EDP1815 achieved an outcome of a 50% improvement from baseline in EASI score (EASI50) by day 70, compared with 0% in the placebo group, showing sustained improvement in those patients responding to EDP1815.

"The data shared today reinforce and extend the previously released results, demonstrating that EDP1815 treatment was well tolerated and resulted in clinically meaningful improvements in measures of atopic dermatitis," said Douglas Maslin, M.Phil, M.B. B.Chir, Dermatology and Pharmacology Physician at Addenbrooke's Hospital and Immunology Clinical Lead of Evelo. "These data show for the first time that treatment with EDP1815 resulted in improvements in patient-reported outcomes on patient experiences such as itch and sleep disturbance, as well as the improvements in all of the physician-reported scores of EASI, SCORAD, IGA, and IGA*BSA. We are planning to initiate a Phase 2 dose-ranging study in the third quarter of this year to evaluate the potential of this novel therapeutic candidate to benefit millions of people worldwide who are living with mild and moderate atopic dermatitis. Together with the previous results in psoriasis, EDP1815 continues to demonstrate the potential to be a safe, effective, well tolerated, oral, broad-spectrum anti-inflammatory therapy."

About the EDP1815 Phase 1b 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 patients with psoriasis or atopic dermatitis. The atopic dermatitis cohort enrolled 24 patients with mild and moderate atopic dermatitis, randomized 2:1 to receive oral administration of the enteric capsule formulation of EDP1815 or placebo once daily, for 56 days, with follow-up off treatment at day 70. Patients were not allowed to use active topical treatments and were not required to use emollients. The primary endpoint was safety and tolerability. Secondary endpoints included a range of established markers of atopic dermatitis.

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 four independent cohorts provide evidence supporting EDP1815's potential to address Th1, Th2 and Th17-mediated inflammation.

In the psoriasis cohorts of the Phase 1b clinical trial, EPD1815 was also observed to limit the systemic production of multiple inflammatory cytokines, including IL-6, IL-8, TNF, and IL-1, which are well-established mediators of potentially harmful effects in patients with inflammatory diseases. Preclinical and clinical data to date showed that EDP1815 achieved this anti-inflammatory activity without inducing immunosuppression. EDP1815 has been observed to be well-tolerated in clinical studies to-date.

About Atopic Dermatitis
Atopic dermatitis, also known as eczema, is a common chronic inflammatory skin disease that affects both children and adults, with a prevalence of up to 3-6% in adults worldwide. It typically presents as a red, intensely itchy rash that may cause lifelong symptoms. Due to the chronic nature and frequency of relapses, atopic dermatitis is associated with a substantial physical and psychosocial burden on patients and their families. It can also occur alongside other atopic diseases including food allergy, asthma, and allergic rhinitis, as these conditions are all associated with an imbalance towards a Th2 inflammatory response – an immune pathway on which EDP1815 has been shown to have potent pre-clinical, and now also clinical, activity.

Patients with atopic dermatitis are often treated with topical medications, which are inconvenient and burdensome in application, leading to poor adherence and reduced efficacy in a real-world setting. Beyond topicals, patients have limited treatment options, especially patients with mild and moderate disease, who represent 80-90% of atopic dermatitis patients worldwide. This group of patients typically do not have access to high-cost, injectable antibody therapies or may be uncomfortable with the toxicity concerns and monitoring requirements of systemic immunosuppressants. There is a large need across the spectrum of disease severity, and especially for these midline, pre-biologic patients, for a safe and well-tolerated oral medicine that resolves the systemic inflammation that drives atopic dermatitis.

Conference Call
Evelo will host a conference call and webcast today at 8:30 a.m. ET with Dr. Benjamin Ehst, M.D., Ph.D., Board-certified Dermatologist, Investigator and Clinical Associate Professor with the Oregon Medical Research Center, to discuss these clinical results and the unmet need in atopic dermatitis. A live webcast containing slides for the event will be available under “News and Events” in the Investors section of Evelo's website at http://ir.evelobio.com. To ask a question during today's call, please dial (866) 795-3242 (domestic) or (409) 937-8909 (international) and refer to conference ID 9528164. 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 is a clinical stage biotechnology company developing orally delivered medicines that act on SINTAX™, the small intestinal axis, and to have 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 defined pharmacological properties.

Evelo currently has four product candidates in development: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases and EDP1908 for the treatment of cancer. 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 timing and results of any clinical trials or readouts for EDP1815, our development plans, and the promise and potential impact of any of our therapies.

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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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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