Evelo Biosciences Completes Enrollment in Phase 1b Clinical Trial Cohort Evaluating EDP1815 in Atopic Dermatitis

October 14, 2020

–Data expected in 1Q 2021–

CAMBRIDGE, Mass., Oct. 14, 2020 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today announced that it has completed enrollment of 24 patients in the Phase 1b clinical trial cohort evaluating EDP1815 in mild to moderate atopic dermatitis. EDP1815 is an investigational oral biologic in development for the treatment of inflammatory diseases.

"Topical therapies are the mainstay of treatment for mild and moderate atopic dermatitis but patient satisfaction and compliance is low, as many find existing regimens too inconvenient or unsatisfactory to support long-term use," said Benjamin Ehst, M.D., Ph.D., Board-certified Dermatologist, Investigator and Clinical Associate Professor with the Oregon Medical Research Center. "Similar to the unmet need in psoriasis, there is an urgent need for a new therapeutic option that can be delivered orally and has a clean safety profile to effectively treat a broad range of patients with atopic dermatitis. I am encouraged by early clinical and biomarker data in psoriasis, which have shown EDP1815 to be well-tolerated and active on systemic inflammation. I am hopeful that these data will be replicated in atopic dermatitis, where I believe EDP1815 could meaningfully change the treatment paradigm for millions of patients."

"We are pleased to announce that we have completed enrollment in our Phase 1b cohort evaluating EDP1815 in atopic dermatitis ahead of schedule, and are grateful to the patients who are participating in the trial, especially in the midst of the ongoing COVID-19 pandemic," said Duncan McHale, M.B.B.S., Ph.D., Chief Medical Officer of Evelo. "The fast pace of enrollment reflects the dissatisfaction with current treatment options and the substantial demand for a new therapy for atopic dermatitis, as well as Evelo's commitment to executing with urgency to deliver on EDP1815's full potential. A range of preclinical data in models of Th2-inflammation, combined with the promising clinical data we have already seen in patients with mild and moderate psoriasis, gives us confidence that we can deliver on the unmet need in atopic dermatitis. We look forward to announcing data early next year."

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 to moderate atopic dermatitis, randomized 2:1 to receive oral administration of 2.76g of the enteric capsule formulation of EDP1815 or placebo once daily, for 56 days. The primary endpoint is safety and tolerability. Secondary endpoints include key validated markers of atopic dermatitis, including the Eczema Area and Severity Index (EASI), SCORing Atopic Dermatitis (SCORAD), Dermatology Life Quality Index (DLQI), and Pruritis Numerical Rating Scale (Pruritis NRS).

About EDP1815
EDP1815 is an investigational oral biologic being developed for the treatment of inflammatory diseases. EDP1815 is a strain of *Prevotella histicola*, selected for its specific pharmacology. In two separate cohorts of a Phase 1b clinical trial in psoriasis, EDP1815 was well tolerated with no overall difference reported from placebo. Clinical activity observed included a reduction in mean Psoriasis Area and Severity Index (PASI) scores vs placebo, as well as a reduction in Lesion Severity Score (LSS). Two weeks following the completion of the dosing period, at day 42, the high dose cohort showed continued reductions from baseline in both mean PASI and LSS, which may be indicative of a sustained clinical effect and dose response. 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.

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 10% 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 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 to moderate disease who may 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.

About Evelo Biosciences
Evelo Biosciences is a clinical stage biotechnology company developing oral biologics that act on SINTAX™, the small intestinal axis, 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 defined pharmacological properties. Evelo's therapies have the potential to be effective, safe, and affordable medicines to improve the lives of people with inflammatory diseases and cancer.

Evelo currently has four product candidates in development: EDP1815, EDP1867 and EDP2939 for the treatment of inflammatory diseases including psoriasis, atopic dermatitis, and COVID-19, and EDP1503 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 June 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.

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

Source: Evelo Biosciences, Inc.