Evelo Biosciences Treats First Patients in Phase 2 Dose-Ranging Trial of EDP1815 for the Treatment of Psoriasis

October 13, 2020

– Interim data expected by mid-2021 –

CAMBRIDGE, Mass., Oct. 13, 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 dosed the first patients in its Phase 2 clinical trial evaluating EDP1815 for the treatment of mild to moderate psoriasis. EDP1815 is an investigational oral biologic in development for the treatment of inflammatory diseases including psoriasis, atopic dermatitis, and COVID-19.

"We are pleased to announce the dosing of the first patients in our Phase 2 clinical trial in mild to moderate psoriasis," said Duncan McHale, M.B.B.S., Ph.D., Chief Medical Officer of Evelo. "In Phase 1b studies, EDP1815 demonstrated an ability to resolve systemic inflammation and provide clinical benefit to patients with psoriasis. Based on these data, EDP1815 may offer an improved profile to existing products and others in development. EDP1815 has the potential to be an effective, well-tolerated, and convenient medicine for millions of patients with mild to moderate psoriasis. Our Phase 2 trial, if successful, will enable us to advance into confirmatory registrational studies, following meetings with health authorities such as the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). We look forward to interim data by mid-2021, as we continue to progress this important therapy toward market."

EDP1815-201 is a double-blind, placebo-controlled, dose-ranging Phase 2 trial designed to evaluate three doses of the enteric capsule formulation of EDP1815 versus placebo in 225 patients with mild to moderate psoriasis over a 16-week treatment period. The primary endpoint is mean reduction in Psoriasis Area and Severity Index (PASI) score at 16 weeks. Key secondary endpoints include other clinical measures of disease such as Physician's Global Assessment (PGA), Body Surface Area (BSA), PGA x BSA, Psoriasis Symptom Inventory (PSI), Dermatology Life Quality Index (DLQI), and Lesion Severity Score (LSS). Interim data from the study is expected by mid-2021.

About EDP1815 in Psoriasis
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 the second and third quarter of 2019, Evelo reported positive Phase 1b interim clinical data in two cohorts of patients with mild to moderate psoriasis. EDP1815 was well tolerated at both doses, with no overall difference reported from placebo. There was a reduction in mean LSS and PASI score after 28 days of dosing in both cohorts who received EDP1815. In the high dose cohort alone, there was a continued reduction in both mean LSS (of 24% vs. placebo of 7%) and PASI score (of 21% vs. placebo of 3%) at 42 days – 14 days following the last dose of the drug. This may indicate 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 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 thickened 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. There is a strong association with psoriatic arthritis, depression, and metabolic syndrome.

Patients with mild to moderate psoriasis are underserved by current treatments, including topical therapies, which do not control systemic inflammation, have low rates of compliance, or in the case of potent 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 to severe disease. Even in this patient population, the majority of eligible patients do not receive biologics, instead opting for topical 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 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 EDP1815 or our other 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 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.

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Source: Evelo Biosciences, Inc.