Evelo Biosciences Announces Dosing of First Patient in Phase 2 Trial of EDP1815 in Atopic Dermatitis

February 17, 2022

CAMBRIDGE, Mass., Feb. 17, 2022 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing SINTAX™ medicines as a new modality of orally delivered treatments for inflammatory disease, today announced that the first patient has been dosed in EDP1815-207, its Phase 2 randomized clinical trial of EDP1815 for the treatment of patients with mild, moderate, and severe atopic dermatitis.

“We are pleased that dosing has begun in the Phase 2 trial to evaluate the potential of this novel product candidate to benefit people worldwide who are living with atopic dermatitis,” said Jonathan Zung, Ph.D., Chief Development Officer of Evelo. “Our previously released Phase 1b data, together with the positive results we recently released from our Phase 2 trial in mild and moderate psoriasis, demonstrate that EDP1815 has the potential to be a safe, effective, well tolerated, oral, inflammation resolving therapy.”

“Patients and prescribers are in need of a therapy that is safe and well tolerated, as well as orally delivered, for the treatment of atopic dermatitis” said Benjamin Ehst, M.D., Ph.D., Board-certified Dermatologist, Investigator and Clinical Associate Professor with the Oregon Medical Research Center, and Chief Investigator of EDP1815-207. “The integrated safety, tolerability, and efficacy data seen in the Phase 2 trial of EDP1815 in psoriasis, along with its oral administration and potential to be affordably priced, could provide meaningful change to the treatment paradigm for patients living with atopic dermatitis.”

Topline results from the Phase 2 clinical trial are expected in 1H 2023.

About the EDP1815 Phase 2 Clinical Trial
EDP1815-207 is a 16-week, multi-center, double-blind, placebo-controlled Phase 2 trial for the treatment of mild, moderate, and severe atopic dermatitis. Approximately 300 patients will be randomized, across approximately 60 sites globally, into one of three cohorts – each cohort has ~100 patients randomized in a 3:1 ratio (75 to EDP1815 and 25 to placebo). Cohort 1 will be administered a dose of 1.6×10^{11} total cells of EDP1815, or matching placebo administered as two capsules once daily. Cohorts 2 & 3 will be administered a dose of 6.4×10^{11} total cells of EDP1815, or matching placebo administered as two capsules once daily or one capsule twice daily, respectively. The primary endpoint is percentage of patients achieving an EASI-50 at week 16. Key physician-reported secondary endpoints are IGA (Investigator Global Assessment) and BSA (Body Surface Area). Key patient-reported secondary endpoints are DLQI (Dermatology Life Quality Index), POEM (Patient-Oriented Eczema Measure), and Pruritus-NRS (Numerical Rating Scale).

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

About Evelo Biosciences
Evelo Biosciences is a clinical stage biotechnology company developing orally delivered product candidates that are designed to act on the small intestinal axis, SINTAX™, 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 their potential to offer 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.

Evelo currently has three product candidates in development: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases. 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 development of EDP1815, the promise and potential impact of EDP1815 and our other product candidates, the timing of and plans for clinical trials, and the timing of clinical trial readouts of EDP1815.

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 three months ended September 30, 2021, 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.

Contacts
Investors:
Kendra Sweeney, 239-877-7474
ksweeney@evelobio.com

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