Evelo Biosciences Announces First Dosing in Phase 1b Clinical Trial of EDP1815 in Psoriasis and Atopic Dermatitis

November 26, 2018

Data Expected in Second Half of 2019

CAMBRIDGE, Mass., Nov. 26, 2018 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (NASDAQ:EVLO) (“Evelo”) a clinical-stage biotechnology company developing monoclonal microbials to engage immune cells in the small intestine and drive changes in systemic biology, today announced first dosing in its Phase 1b clinical trial of EDP1815 for the treatment of psoriasis and atopic dermatitis. EDP1815 is Evelo’s second monoclonal microbial product candidate being developed for the treatment of inflammatory diseases.

"Psoriasis and atopic dermatitis patients are underserved by current medicines, particularly in the moderate patient populations, where the potential efficacy, tolerability and convenience benefits of monoclonal microbials could be profound," said Andrea Itano, Ph.D., head of immuno-inflammatory diseases at Evelo. "Monoclonal microbials may also have broader therapeutic applicability for many other inflammatory diseases. Alongside the disease-specific exploratory endpoints for atopic dermatitis and psoriasis, this study will also measure biomarkers such as Th1, Th2 and Th17, which may help define the potential for EDP1815 to treat a broader range atopic and arthritic diseases."

About Clinical Trial EDP1815-101

EDP1815-101 is a placebo-controlled Phase 1b that will investigate the safety and tolerability of EDP1815 in 96 healthy volunteers and in patients with mild or moderate psoriasis or atopic dermatitis. Exploratory endpoints include the effect of EDP1815 on validated clinical measures of disease and a range of additional pharmacodynamic markers. Evelo expects to report initial clinical data from this trial in the second half of 2019.

About Evelo Biosciences

Evelo Biosciences, Inc. is a clinical-stage biotechnology company developing monoclonal microbials, a new modality of medicines designed to act on the gut-body network. Evelo’s product candidates are orally-delivered, single strains of microbes, selected for defined pharmacological properties. They are intended to modulate systemic immunology and biology by acting on multiple naturally evolved biological pathways that link the small intestine to the rest of the body. Evelo believes that monoclonal microbials have the potential to be broadly applicable across many diseases including inflammation, cancer and autoimmune diseases.

Evelo currently has three product candidates, EDP1066 and EDP1815 for the treatment of inflammatory diseases and EDP1503 for the treatment of cancer, for which ten clinical readouts are expected during 2019 and 2020. Evelo is also advancing additional candidates 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 the timing and results of EDP1815-101 and other clinical studies and readouts, our development plans, the promise and potential impact of any of our monoclonal microbials, and the timing of and plans to initiate clinical studies of EDP1066 and EDP1503.

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 September 30, 2018 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, 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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