Evelo Provides Update on Recent Positive EDP1815 Regulatory Interactions on Phase 2 Trial Design Resulting in Shorter Development Timeline to Registration

January 10, 2020

-- EDP1815 Phase 2 Interim Data in Psoriasis Expected by Year-End 2020 --

CAMBRIDGE, Mass., Jan. 10, 2020 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today provided an update on recent positive regulatory interactions on the EDP1815 Phase 2 trial design, resulting in a reduction in the overall development plan timeline to registration.

“The immunological effects of the small intestinal axis (“Sintax”), the connections between the small intestine and the body’s immune system, are the foundation for Evelo’s product candidates. We are harnessing the newly discovered biology of Sintax to develop a new class of oral medicines that modulate clinically validated cytokines to treat all stages of disease. In 2019, we reported positive clinical data with EDP1815 in individuals with psoriasis, which was the first clinical evidence of the promise that Sintax holds as a new drug target. Our strategy is to develop a new standard of care for millions of patients with chronic immunological diseases and cancer,” said Simba Gill, Ph.D., chief executive officer of Evelo.

“EDP1815 has the potential to address the unmet needs of millions of individuals with psoriasis who need an effective, safe, convenient, and affordable treatment option. Based on discussions with global regulatory agencies, including the FDA, we have finalized the design of our EDP1815 Phase 2 trial, resulting in a reduction in the overall development plan timeline to registration. The trial design will enable us to rapidly and efficiently highlight EDP1815’s potential benefits to individuals with psoriasis with a commercially attractive formulation and dose in advance of a potential Phase 3 program,” continued Dr. Gill. “In addition, we continue to explore the breadth of our platform, with further clinical readouts for our existing portfolio across cancer and inflammatory diseases expected this year. We also plan to initiate a Phase 1b trial in asthma for EDP1867, a new clinical candidate for inflammatory diseases. We will pursue these clinical programs alongside our broad research efforts to uncover the full potential of Sintax biology.”

EDP1815 – Phase 2 study in mild to moderate psoriasis
In the second and third quarter of 2019, Evelo reported positive Phase 1b interim clinical data in two cohorts of individuals 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 Lesion Severity Score 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 Lesion Severity Score (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[1]. This may indicate a sustained clinical effect and dose response.

Evelo has agreed upon the design of the EDP1815 Phase 2 clinical trial with global regulatory agencies. The dose ranging study will evaluate three doses of a new, improved formulation of EDP1815 versus placebo in approximately 180 individuals. The primary endpoint will be the mean reduction in PASI score at 16 weeks. Evelo expects to initiate the trial in the second quarter of 2020 and to announce interim data by the end of 2020.

Subject to the Phase 2 clinical data, this study design may enable Evelo to advance directly into Phase 3 registrational studies in 2021. Furthermore, the recent regulatory interactions indicate that Evelo may be able to conduct a smaller overall Phase 3 program than expected, thereby reducing the development timeline to registration.

Additional Anticipated 2020 Milestones

EDP1815 – Phase 1b new formulation in mild to moderate psoriasis

- Initial data from an additional cohort in the EDP1815 Phase 1b trial to evaluate a new formulation in up to 24 individuals with mild to moderate psoriasis in the second quarter of 2020.

EDP1815 – Phase 1b new formulation in mild to moderate atopic dermatitis

- Initial data from the Phase 1b clinical trial evaluating a new formulation of EDP1815 in a cohort of 24 individuals with mild to moderate atopic dermatitis in the second quarter of 2020.

EDP1066 – Phase 1b new formulation in mild to moderate atopic dermatitis

- Initial data from the Phase 1b clinical trial evaluating a new formulation of EDP1066 in a cohort of individuals with mild to moderate atopic dermatitis in the first quarter of 2020.

EDP1867 – Phase 1b clinical trial in asthma

- Initiation of a Phase 1b clinical trial in individuals with asthma evaluating EDP1867, a new clinical candidate for inflammatory diseases, in the second half of 2020.

EDP1503 – Phase 1/2 in oncology

- Further data from the ongoing Phase 1/2 clinical trial evaluating EDP1503 in combination with Merck’s anti-PD-1, KEYTRUDA® (pembrolizumab), in individuals with microsatellite colorectal cancer, triple-negative breast cancer or other tumor types who have relapsed on prior PD-1/L1 inhibitor treatment, in the first half of 2020.

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[1] This study was not sufficiently powered to detect statistically significant differences in clinical effect between treatment groups.

About Evelo Biosciences
Evelo Biosciences, Inc. is a clinical stage biotechnology company developing oral biologics that act on the small intestinal axis (Sintax) with systemic therapeutic effects. The small intestinal axis plays a central role in governing the immune, metabolic and neurological systems. The company's first product candidates are monoclonal microbials, single strains of microbes selected for defined pharmacological properties. They have been observed in pre-clinical models to have systemic dose-dependent effects, modulating multiple clinically validated pathways. Evelo's therapies have the potential to be effective, safe and affordable medicines to improve the lives of people with chronic diseases and cancer.

Evelo currently has four product candidates, EDP1815, EDP1066, and EDP1867 for the treatment of inflammatory diseases, and EDP1503 for the treatment of cancer. Evelo is also advancing additional oral biologics through preclinical development 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 our development plans, the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, the timing of and plans for clinical studies of EDP1867, EDP1815, EDP1066 and EDP1503, and the timing and results of any clinical studies or readouts.

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, 2019, 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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