Evelo Biosciences Announces Dosing of First Patient in Phase 1/2 Clinical Trial of EDP1503 in Combination with KEYTRUDA® (pembrolizumab) in Multiple Oncology Indications

January 4, 2019

-- Initial Clinical Data Expected in First Half of 2020 --

CAMBRIDGE, Mass., Jan. 04, 2019 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (NASDAQ:EVLO) (“Evelo”) a biotechnology company developing monoclonal microbials, a new modality of oral biologic medicines, today announced that it has dosed the first patient in its Phase 1/2 clinical trial of EDP1503 in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 therapy. EDP1503 is an orally delivered monoclonal microbial product candidate being developed for the treatment of cancer.

This open-label clinical trial will evaluate the safety, tolerability, immune response markers, and overall response rates achieved with EDP1503 in combination with KEYTRUDA® in up to 120 patients across three groups: microsatellite stable colorectal cancer; triple-negative breast cancer; and patients across multiple tumor types who have relapsed on prior PD-1/L1 inhibitor treatment.

Patients will receive daily EDP1503 monotherapy for two weeks followed by treatment with daily EDP1503 in combination with KEYTRUDA®. The study will evaluate biomarkers identified from paired biopsies taken before and after the two-week run-in, as well as clinical outcomes observed over the course of the trial. Evelo expects to report initial clinical data from the trial in the first half of 2020.

“This clinical trial of EDP1503 will allow us to explore the potential synergies between EDP1503 and KEYTRUDA® and offers the potential to treat multiple cancer types that are otherwise poorly responsive to checkpoint inhibitors,” said Humphrey Gardner, M.D., FCAP, chief of medical oncology at Evelo.

In preclinical studies orally delivered EDP1503 shows activation of multiple clinically validated systemic immune pathways which are complementary to and potentially synergistic with checkpoint inhibitors. Effects include increased CXCL9 and CXCL10 production in the tumor microenvironment, augmentation of NK and T cell infiltration to the tumor site as well as upregulation of MHC Class I expression in tumors.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About Evelo Biosciences

Evelo Biosciences, Inc. is a clinical-stage biotechnology company developing monoclonal microbials, a new modality of oral biologic medicines. Evelo’s product candidates are orally-delivered, single strains of microbes, selected for defined pharmacological properties. They are developed to engage immune cells in the small intestine and drive changes in systemic biology. Evelo believes that monoclonal microbials have the potential to be broadly applicable across many diseases including immunoinflammatory, cancer, autoimmune, metabolic, and neuroinflammatory diseases.

Evelo currently has three product candidates in clinical development, 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 statements regarding the promise and potential impact of any of our monoclonal microbials or preclinical or clinical trial data, timing of and plans to initiate clinical studies of EDP1503, and the timing and results of any clinical studies of EDP1503, EDP1066 and 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: 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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