Evelo Enters into Clinical Trial Collaboration Agreement with Merck

November 27, 2018

-- Initiation of Phase 1/2 Combination Clinical Trial with Evelo's Monoclonal Microbial, EDP1503, and KEYTRUDA® (pembrolizumab) Across Various Indications Expected in First Half of 2019 --

CAMBRIDGE, Mass., Nov. 27, 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 that it has entered into a clinical trial collaboration agreement with Merck (known as MSD outside the US and Canada). The collaboration will evaluate EDP1503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in multiple cancer indications. EDP1503 is an orally delivered monoclonal microbial product candidate being developed for the treatment of cancer.

The planned Phase 1/2 trial will evaluate the safety, tolerability, immune response markers and overall response rates (ORRs) achieved with EDP1503 in combination with KEYTRUDA® (pembrolizumab) in three groups of patients: microsatellite stable colorectal cancer; triple-negative breast cancer; and patients across multiple tumor types who have relapsed on prior PD-1/L1 inhibitor treatment. Evelo expects to commence this clinical trial in the first half of 2019 and plans to enroll up to 120 patients in this non-comparative, single-arm, multicenter clinical study.

''We are very pleased to collaborate with Merck, one of the world leaders in immuno-oncology, in our clinical investigation of EDP1503 in combination with Keytruda®. We have shown preclinically that oral delivery of EDP1503 activates multiple systemic immune pathways across clinically validated mechanisms of tumor immune stimulation which are complementary to and potentially synergistic with checkpoint inhibitors," said Humphrey Gardner, M.D., FCAP, chief of medical oncology at Evelo. "These immune-activation properties of EDP1503, including upregulation of MHC Class I expression, increased production of CXCL9 and CXCL10, and augmentation of NK cell infiltration point to the potential to offer a treatment approach in tumors that have, to date, proved unresponsive to checkpoint inhibitor monotherapy, such as microsatellite stable colorectal cancer."

EDP1503 is currently being evaluated in an investigator-sponsored Phase 2a clinical trial in combination with KEYTRUDA® in patients with metastatic melanoma (CT.gov: NCT03595683). First patient dosing in this study is expected by the end of 2018.

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

About EDP1503

EDP1503 is Evelo's first monoclonal microbial oncology product candidate and is being developed under the umbrella of its exclusive worldwide license with the University of Chicago. Under this license, Evelo has exclusive patent rights related to the administration of microbes to treat cancer, including in combination with checkpoint inhibitors. The patent rights describe many genera of microbes and will provide broad patent protection. A US patent covering the combination of *Bifidobacteria* and checkpoint inhibitors to treat cancer was granted in January 2018. Preclinical data suggests that EDP1503 is active through different and complementary immune mechanisms beyond those targeted by checkpoint inhibitors. In preclinical models, EDP1503 alone stimulated upregulation of the immune response to tumors, delayed tumor progression and, when combined with a checkpoint inhibitor, showed additive effects in delaying tumor progression.

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 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; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; 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, 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.

Contact:
Evelo Biosciences
Stefan Riley
617-704-2333
stefan@evelobio.com

Source: Evelo Biosciences, Inc.