Evelo Biosciences Announces Biomarker Data Showing EDP1815 is an Orally Delivered Dual Cytokine Inhibitor for Inflammatory Diseases

March 2, 2020

CAMBRIDGE, Mass., March 02, 2020 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today announced biomarker data for EDP1815, its lead inflammation product candidate. Interim data from individuals in the ongoing Phase 1b clinical trial showed marked activity on multiple individual systemic markers of inflammation, including interleukin-6 (IL-6) and interleukin-8 (IL-8). IL-6 and IL-8 are well-established mediators of potentially harmful effects in patients with inflammatory diseases and these data support the therapeutic potential of EDP1815 to treat classic inflammatory diseases such as psoriasis.

“These results support our central thesis that we can treat systemic inflammation by targeting SINTAX™, the small intestinal axis. This radical new understanding of how inflammation is controlled is the foundation of our approach to developing effective, safe, orally delivered medicines,” said Mark Bodmer, Ph.D., chief scientific officer of Evelo. “This analysis of specific clinical biomarkers provides further evidence that EDP1815 has the potential to address systemic inflammation by targeting the functional connections in the small intestine with the rest of the body. Concurrent reductions in the production of multiple inflammatory cytokines by a well-tolerated oral agent is a unique profile for the treatment of diseases involving inflammation.”

Evelo previously reported interim data showing reduced production of systemic markers of inflammation in individuals with mild to moderate psoriasis dosed with EDP1815. The detailed analysis of the previously reported data show that EDP1815 highlights the individual inflammatory cytokines and chemokines that were modulated.

Six cytokines were reliably detected in the biomarker assay. The results for IL-6 and IL-8 are shown in the waterfall plots below. Treatment with EDP1815 caused a pronounced downward shift in production compared to placebo during the 28-day treatment period. Similar, slightly less pronounced reductions were seen for TNFa and IL1b. No effect was seen on IFN-g or IL-10.

A Media Snippet accompanying this announcement is available by clicking on the image or link below:

EDP1815 reduces production of IL-6 and IL-8 from human blood cells after 28 days of treatment

EDP1815

Evelo plans to study EDP1815 in a range of inflammatory diseases following interim data from a planned Phase 2 trial in psoriasis, expected in late 2020. The effect of EDP1815 on IL-6 and IL-8 induction is also notable given the emerging evidence of their potential role in driving pathogenic effects and lung damage following infection with a range of viruses including influenza, coronaviruses (SARS, MERS and SARS-CoV-2), and respiratory syncytial virus. Based on these new biomarker data, Evelo is in the early stages of evaluating opportunities to develop EDP1815 for the treatment of diseases caused by viral infection, including influenza and coronaviruses (SARS-CoV-2).

About the Biomarker Analysis Protocol
Blood samples were taken at baseline and after 28 days of daily oral administration of EDP1815 (n=20) or placebo (n=18) from patients in Evelo’s ongoing clinical study in mild to moderate psoriasis. Whole blood was incubated with a broad inflammatory activator, lipopolysaccharide (LPS). The waterfall plots show the difference between the baseline value and after 28 days of treatment. All patients from both low and high dose EDP1815 cohorts are shown.

About Evelo Biosciences

Evelo Biosciences is a clinical stage biotechnology company developing oral biologics that act on SINTAX™, the small intestinal axis, with systemic therapeutic effects. SINTAX 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. 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, EDP1867, and EDP2939 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 EDP1815, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 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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