Evelo Biosciences Reports that EDP2939, its First Oral Extracellular Vesicle Product Candidate, Commenced Dosing in a Phase 2 Psoriasis Trial

February 27, 2023

– Completed first blinded, placebo-controlled cohort in human volunteers with no safety or tolerability concerns –

– Dosing in EDP2939 Phase 2 trial in patients with moderate psoriasis has been initiated –

– EDP2939 Phase 2 data in psoriasis anticipated in 2H 2023 –

CAMBRIDGE, Mass., Feb. 27, 2023 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a novel platform of orally delivered anti-inflammatory medicines acting on the small intestinal axis, SINTAX, today announced that its first extracellular vesicle (EV) product candidate, EDP2939, has progressed to dosing in a Phase 2 psoriasis clinical trial after completing a safety and tolerability review from a first cohort of human volunteers. Safety and tolerability assessment of multiple ascending dose cohorts continues.

"This is a milestone for both EDP2939 and Evelo's broader platform of orally-delivered EVs," said Evelo's Chief Medical Officer, Duncan McHale, M.B.B.S., Ph.D. "It is the first time that a potential bacterial EV medicine has been delivered orally to humans. Safety and tolerability are a central part of Evelo's vision to develop medicines to treat all stages and all types of inflammatory diseases. We have now started dosing in the Phase 2 part of the trial in patients with moderate psoriasis."

Mark Bodmer, Ph.D., President of R&D and Chief Scientific Officer of Evelo added, "EVs and EDP2939 show great promise as a new type of SINTAX medicine with potential for biologic-like efficacy based on three factors: (1) the high intrinsic potency of EVs in preclinical models; (2) the number and concentration of EVs that can be delivered in a single capsule; and (3) the delivery to the target site of the proximal small intestine. We look forward to reporting EDP2939 psoriasis efficacy results, expected in the second half of this year."

About the EDP2939 Trial
EDP2939-101 is a multi-center randomized, placebo-controlled, Phase 1/2 trial evaluating the safety, tolerability and clinical efficacy of EDP2939. Part A (Phase 1) of the trial is designed to determine safety and tolerability in human volunteers at multiple ascending doses. The primary endpoints of Part A are safety endpoints: AEs, SAEs, vital signs, safety laboratory tests, and ECGs.

Part B (Phase 2) is designed to determine the efficacy of EDP2939 in patients with moderate plaque psoriasis at the proposed therapeutic dose. The primary endpoint is the proportion of patients who achieve an outcome of a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI) score (a PASI-50 response) after 16 weeks of daily oral administration of EDP2939 or placebo. Secondary endpoints include several physician- and patient-reported psoriasis outcomes, as well as further safety evaluation. The trial will comprise approximately 110 patients randomized 1:1 to receive a single capsule of either EDP2939 or a matching placebo.

About Evelo Biosciences
Evelo Biosciences is a clinical stage biotechnology company developing a novel platform of orally delivered anti-inflammatory medicines acting on the small intestinal axis, SINTAX, with systemic therapeutic effects. The small intestine plays a central role in governing inflammation throughout the body. The Company's product candidates are pharmaceutical preparations of single strains of microbes or their extracellular vesicles (EVs). Evelo initially is developing EDP1815 in psoriasis and atopic dermatitis and EDP2939 in psoriasis. Evelo's vision is to create therapies that are effective, safe, well-tolerated, and affordable to improve the lives of the billions of people living with inflammatory diseases. If shown to be effective in inflammatory disease mediated by the Th1, Th2 or Th17 inflammatory pathways, these same investigational medicines could be effective in additional inflammatory diseases, such as psoriatic and other forms of arthritis, asthma, allergy, and inflammatory bowel disease.

For more information, please visit www.evelobio.com and engage with Evelo on LinkedIn.

Forward Looking Statements
This press release contains forward-looking statements, including 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 the expected timing of, and data results from, trials and clinical studies involving the Company's product candidates .

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 projected cash runway; our need for additional funding; our ability to meet our debt obligations (including restrictive and operational covenants and terms of refinanced debt); our ability to cure or satisfactorily resolve any default arising from our debt agreements; our limited operating history; our unproven approach to therapeutic intervention; our ability to address regulatory questions and the likelihood of regulatory filings and approvals; 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 operate with a reduced workforce, to manage potential growth and to retain key personnel, particularly following a significant downsizing; 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; the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; 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 period ended September 30, 2022, and our other reports filed with the United States Securities and Exchange Commission, 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.

Contacts

Investors:
ir@evelobio.com

Media:
media@evelobio.com