Evelo Biosciences Presents New Preclinical Data for Anti-Tumor Effects of Orally Delivered Microbial Extracellular Vesicles at the SITC 35th Anniversary Annual Meeting

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-- EDP1908 demonstrates potent anti-tumor effects in murine models of cancer --
-- Oral extracellular vesicles have potential to be a completely novel mechanism of I/O therapy --

CAMBRIDGE, Mass., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO) a clinical stage biotechnology company developing a new modality of orally delivered medicines which act in the small intestine with systemic effects, today announced preclinical data for EDP1908, its extracellular vesicle product candidate for the treatment of cancer, in a poster presentation at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting. The data show that orally administered EDP1908 had anti-tumor effects that surpassed both checkpoint inhibitors and orally delivered microbial strains in preclinical models.

"We are discovering and developing products that engage the small intestinal axis, SINTAX™. They control systemic immune and inflammation responses by their action in the small intestine, which then sends potent immunomodulatory signals throughout the body. We have shown the potential of SINTAX medicines in the clinic and are exploring ways to optimize their effects using new forms and formulations," said Mark Bodmer, Ph.D., Chief Scientific Officer of Evelo. "Today, we are unveiling new foundational data showing that an orally administered bacterial extracellular vesicle (EV) has striking preclinical anti-tumor effects without systemic distribution. These data suggest that EVs of appropriately selected microbes have the potential to drive an entirely new type of I/O therapy by engaging SINTAX."

In the preclinical study presented at SITC, tumor-bearing mice were treated with ascending doses of either oral EDP1908 or the parental microbial strain of EDP1908, or with anti-PD-1. Treatment with EDP1908 resulted in superior tumor growth control versus either the parent microbial strain or anti-PD-1 therapy, with a dose-dependent reduction of tumor growth. The effects were also at least comparable to those reported in the literature for intra-tumoral immune stimulators.

Treatment with EDP1908 activated IFNγ-positive cytolytic and helper lymphocytes, dendritic cells, and interferon gamma-induced protein 10 (IP-10) in the tumor microenvironment. Fluorescent biodistribution analysis showed that EDP1908 was not detected outside the gastrointestinal tract. These data suggest that EDP1908 activates innate immunity by acting locally on host immune cells in the gut to trigger distal immune responses within the tumor microenvironment, with no apparent adverse safety or tolerability effects preclinically.

EDP1908 is now in preclinical and manufacturing development.

About Extracellular Vesicles
Some bacteria produce EVs that share molecular content with the parent bacterium, in particles that are roughly one-one thousandth the volume and are not capable of self-replicating. EVs enable bacterial communication and survival during stress, host-immune modulation, material exchange and cell-cell interactions. EV's significantly smaller size compared to microbes enables improved distribution and target engagement.

About Evelo Biosciences
Evelo Biosciences is a clinical stage biotechnology company developing orally delivered medicines 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 pharmaceutical preparations of 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 inflammatory diseases and cancer.

Evelo currently has five product candidates in development: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases including psoriasis, atopic dermatitis, and COVID-19, and EDP1503 and EDP1908 for the treatment of cancer. Evelo is advancing additional product candidates 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 the development of EDP1908, the promise and potential impact of EDP1908 or our other product candidates, and the timing of and plans for clinical trials of EDP1908.

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: *the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business*; *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, 2020, 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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