Evelo Biosciences Expands Clinical Programs and Provides 2021 Guidance on Key Milestones

January 7, 2021

-- Expand EDP1815 Phase 2 program to include atopic dermatitis; interim clinical results expected in 1Q 2022 --

-- Accelerate delivery of interim clinical data from EDP1815 Phase 2 psoriasis trial to 2Q 2021; full dataset expected 2H 2021 --

-- Advance novel anti-inflammatory product candidate EDP1867 in atopic dermatitis into clinic in 1Q 2021; data expected 4Q 2021 --

-- Prepare to advance first extracellular vesicle (EV) product candidates into the clinic in 2022: EDP2939 for inflammation and EDP1908 for oncology --

CAMBRIDGE, Mass., Jan. 07, 2021 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered product candidates which act in the small intestine to drive systemic effects, today announced its strategic priorities and anticipated milestones for 2021.

“2020 was a pivotal year for Evelo. We reported positive clinical data for EDP1815 in both atopic dermatitis and a human experimental model of inflammation, showing translation of preclinical results into humans. The small intestinal axis, SINTAX^{TM}, offers the potential for a new class of oral, well-tolerated medicines giving broad resolution of systemic inflammation,” said Simba Gill, Ph.D., Chief Executive Officer of Evelo. “In parallel, we invested in manufacturing capabilities and supply chain to advance our ability to deliver our products at commercial scale. This clinical and manufacturing progress positions us to achieve our foundational vision of going beyond the limits of current biotechnology to develop products that are effective, safe, convenient, and affordable for patients globally at all stages of inflammatory diseases and cancer.”

In 2021, Evelo plans to focus on:

1. Advancing EDP1815, its lead anti-inflammatory product candidate, through Phase 2 dose-ranging trials, as well as formulation and manufacturing optimization, towards potential Phase 3 trials in mild to moderate psoriasis and atopic dermatitis. Psoriasis is a chronic skin disease impacting up to 3% of people globally. Atopic dermatitis is the most common chronic skin disease, impacting an estimated 10% of adults and 25% of children globally. Monoclonal antibodies and JAK inhibitors are not typically used in mild to moderate patients, leaving significant unmet need.
2. Expanding the international reach of EDP1815 in hospitalized patients with COVID-19. The TACTIC-E trial recently received regulatory approval in Mexico, adding 7 hospitals to the trial.
3. Generating initial clinical data on the safety and pharmacology of the Company’s next anti-inflammatory product candidate, EDP1867, in atopic dermatitis.
4. Progressing its first extracellular vesicle (EV) candidates EDP2939 for inflammatory diseases and EDP1908 for oncology into first-in-human studies in 2022; and
5. Expanding its discovery and development pipeline into new areas within inflammatory diseases, as well as exploring opportunities beyond its initial therapeutic focus areas of inflammatory diseases and oncology.

“We have observed in multiple clinical trials that we can harness the small intestinal axis to control inflammation and immunity elsewhere in the body,” said Mark Bodmer, Ph.D., President of Research and Development of Evelo. “Our potential products bypass the complexities of the resident microbiota to modulate host immunity directly via SINTAX, creating well-defined, broadly applicable drugs with a favorable safety and tolerability profile. Our lead inflammation program, EDP1815, appears to mimic natural physiological processes of resolution of most types of inflammation, Th1, Th2 and Th17, without the side effect of immunosuppression. The clinical potential for patients is vast, given the range of diseases which involve inflammation, including COVID-19. EVs are a surprising new form of SINTAX medicines. Their small size results in a great increase in preclinical potency and ability to reach and engage host cells in the small intestine. Moving EDP2939 and EDP1908 towards the clinical is a major goal for 2021.”

Expected 2021 Milestones

EDP1815 – Psoriasis

- Initiation of Phase 1b tablet formulation trial in 1Q 2021; data in 3Q 2021
- Interim data from Phase 2 trial in 2Q 2021
- Full data from Phase 2 trial in 2H 2021
- Initiation of Phase 3 trial in 1H 2022, depending on positive Phase 2 data

EDP1815 – Atopic Dermatitis

- Subject to regulatory approval, initiation of Phase 2 trial in 3Q 2021
- Interim data from Phase 2 trial in 1Q 2022
- Initiation of Phase 3 trial in 2022, depending on positive Phase 2 data

EDP1815 – COVID-19

- Data from Phase 2 Rutgers University trial in 2Q 2021
- Interim safety data and futility analysis from Phase 2/3 TACTIC-E trial in 2Q 2021

EDP1867 – Atopic dermatitis

- Initiation of Phase 1b trial in 1Q 2021; data expected in 4Q 2021

EDP2939 – Inflammation

- Initiation of Phase 1 trial in 2022

EDP1908 – Oncology

- Initiation of Phase 1 trial in 2022

About Evelo Biosciences
Evelo Biosciences is a clinical stage biotechnology company developing orally delivered product candidates that are designed to 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 the potential to offer 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 four product candidates in development: EDP1815, EDP1867, and EDP2939 for the treatment of inflammatory diseases 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 EDP1815, EDP1867, EDP2939, and EDP1908, the promise and potential impact of any of our product candidates, the timing of and plans for clinical trials of EDP1815, EDP1867, EDP2939, and EDP1908, and the timing and results of any clinical trials 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: 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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