# Evelo Biosciences Provides Updated Guidance on Advancing Clinical Inflammation Programs

April 14, 2022

–Guidance on registration trials for EDP1815 in psoriasis expected in 3Q 2022–
–Data from initial cohort of patients in Phase 2 trial of EDP1815 in atopic dermatitis expected 1Q 2023–
–Faster release capsule cohort to be added to on-going Phase 2 trial of EDP1815 in atopic dermatitis; data expected 1H 2023–

CAMBRIDGE, Mass., April 14, 2022 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing SINTAX™ medicines as a new modality of orally delivered treatments for inflammatory disease, today provided an update on the progress of its lead program in inflammation, EDP1815, and announced it will put the EDP1867 program on hold following completion of a Phase 1 clinical trial.

“Key opinion leader and market research feedback on the data from our Phase 2 trial of EDP1815 in psoriasis has supported the potential of EDP1815 to change the standard of care for millions of patients who suffer from all stages of psoriasis and are in need of an effective, safe, and well-tolerated oral medicine to treat their disease,” said Simba Gill, Ph.D., Chief Executive Officer of Evelo. “During the third quarter of this year, we expect to discuss the path to registration for EDP1815 in psoriasis with health authorities.”

Dr. Gill continued, “In addition, we are recruiting ahead of plan in our Phase 2 trial of EDP1815 in atopic dermatitis, and now expect data from this study to be available in the first quarter of 2023. Also, given the positive data we announced recently from a capsule with a faster and more consistent release profile, we intend to add a cohort of patients to the on-going Phase 2 trial of EDP1815 in atopic dermatitis to evaluate this capsule. The faster release profile has the potential to provide increased responses and enhanced efficacy in patients. We expect data from this additional cohort to be available in the first half of 2023.”

**EDP1815 – Psoriasis**

- Evelo previously released positive clinical data, confirmatory cytokine biomarker data, and post-treatment follow-up findings from its Phase 2 clinical trial of EDP1815 in mild and moderate psoriasis.
- Along with efficacy data, Evelo reported that EDP1815’s safety and tolerability data were comparable to placebo in the trial.
- Evelo plans to meet with health authorities to discuss the path forward to registration trials in psoriasis during 3Q 2022.

**EDP1815 – Atopic Dermatitis**

- The on-going recruitment for the Phase 2 atopic dermatitis trial is ahead of plan.
- In March 2022, results from an ongoing Phase 1 single center clinical trial in healthy volunteers demonstrated that a capsule with an improved release profile was able to deliver EDP1815 higher up in the small intestine in 15 of 17 healthy volunteers. Preclinical data have shown that the higher EDP1815 is released in the small intestine, the greater the pharmacological effect.
- Given these data, Evelo intends to add a cohort to its on-going Phase 2 trial of EDP1815 in mild, moderate, and severe atopic dermatitis. Patients in this cohort will receive 1 capsule of EDP1815 with the faster release profile once daily.
- Data from the first 3 cohorts of the Phase 2 atopic dermatitis trial will be available in 1Q 2023 and the additional 4$^{th}$ cohort by 1H 2023.

**EDP1867 – Atopic Dermatitis**

- Data from the Phase 1b clinical trial of EDP1867 (n=52, with 40 participants who had at least one dose of EDP1867) showed it was safe and well-tolerated in both healthy volunteers and patients with moderate atopic dermatitis across all doses tested.
- No clear evidence of clinical benefit was observed in the small set of patients (n=15) with atopic dermatitis who received the lower dose of EDP1867 and provided analyzable data at week 8.
- The Company will put the EDP1867 program on hold to focus its efforts on its lead inflammation programs EDP1815 and EDP2939.

**About Evelo Biosciences**
Evelo Biosciences is a clinical stage biotechnology company developing orally delivered product candidates that are designed to act on the small intestinal axis, SINTAX™, 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 their 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 a broad range of inflammatory diseases.

Evelo currently has two product candidates in development for inflammatory diseases: EDP1815 and EDP2939. 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 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 development of EDP1815 and our other product candidates, the promise and potential impact of our product candidates,*

*the timing of and plans for clinical trials, and the timing and results of clinical trial 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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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