# Evelo Biosciences Announces Further Positive Interim Phase 1b Clinical Data in Psoriasis and Reports Third Quarter 2019 Financial Results

November 5, 2019

--EDP1815 was Well Tolerated with No Overall Difference Reported from Placebo--
--Reduction in Mean Lesion Severity Score (LSS) at 28 Days Consistent between High and Low Dose Cohort--
-- Dose Response Trends Observed in LSS and PASI at Day 42--
--EDP1815 Phase 2 Study Initiation Expected in Early 2020--
--Further Clinical Support for Validation of Evelo Platform--
-- Management to Host Conference Call at 8:30 a.m. EST--

CAMBRIDGE, Mass., Nov. 05, 2019 (GLOBE NEWSWIRE) -- Evelo Biosciences, Inc. (Nasdaq:EVLO), a clinical stage biotechnology company developing a new modality of orally delivered, systemically acting biologics, today announced third quarter 2019 financial results. Additionally, in a separate press release, the Company announced positive interim clinical data in a Phase 1b trial in individuals with mild to moderate psoriasis being treated with a high dose of EDP1815, its clinical candidate for the treatment of a range of inflammatory diseases.

“We now have further clinical data that support our potential ability to treat systemic inflammatory disease through oral delivery of pharmaceuticals to the small intestinal axis,” said Simba Gill, Ph.D., chief executive officer of Evelo. “The clinical activity demonstrated by EDP1815 in psoriasis further validates our platform and highlights Evelo’s potential to bring new medicines with the potential to be effective, safe, convenient and affordable to millions of people living with chronic diseases.”

**Inflammation**

**Interim Clinical Data Highlights**

**About the EDP1815 Phase 1b clinical trial in mild to moderate psoriasis, high dose cohort**

Eighteen individuals with mild to moderate psoriasis were randomized 2:1 to receive a daily oral administration of 2.76g (5x or high dose) of EDP1815 or placebo for 28 days. The primary endpoint is safety and tolerability. Secondary and exploratory endpoints include lesion severity score (LSS) and Psoriasis Area and Severity Index (PASI), both measures of clinical activity, as well as cellular histological biomarkers and blood immune cell biomarkers taken from biopsies and blood samples at the start and end of the dosing period, respectively. Safety and tolerability and secondary clinical endpoints are also measured at day 42, 2 weeks after completion of dosing.

**EDP1815 – positive interim Phase 1b clinical data at high dose**

- In a separate press release, Evelo reported positive interim clinical data from the high dose cohort in its Phase 1b trial of EDP1815 in mild to moderate psoriasis.
- EDP1815 continued to be well tolerated in this cohort, with no overall difference reported from placebo.
- At the end of the 28-day dosing period, the high dose cohort showed a mean reduction in LSS consistent with previously reported data for a low dose cohort.
- Two weeks following the completion of the dosing period, at day 42, the high dose cohort showed continued reductions from baseline in both mean LSS and PASI, which may be indicative of a sustained clinical effect and dose response.
- A range of histological and molecular biomarkers were measured in the high dose cohort, with trends in line with the clinical effects of EDP1815 at the cohort level.
- Evelo plans to advance EDP1815 into Phase 2 in early 2020. This placebo-controlled dose and formulation selection trial will investigate daily dosing of EDP1815 in mild to moderate psoriasis patients over 16 weeks. Evelo expects to report initial data from the trial in late 2020.

**Anticipated Milestones**

**EDP1815 – Phase 1b new formulation in psoriasis and atopic dermatitis**

- Given the newly released positive EDP1815 data and the planned Phase 2 trial, Evelo will not enroll any further cohorts of individuals with psoriasis in the ongoing Phase 1b clinical trial.
- The Company expects to report initial clinical data from a cohort of individuals with mild to moderate atopic dermatitis to be dosed with a new formulation in the second quarter of 2020.

**EDP1066 – Phase 1b new formulation in atopic dermatitis**

- Evelo expects to report initial clinical data from a cohort of individuals with mild to moderate atopic dermatitis, dosed with a new formulation, in the first quarter of 2020.

**Oncology**

**Clinical Studies and Anticipated Milestones**

**EDP1503 - Phase 1/2**

- Evelo is conducting a Phase 1/2 clinical trial of EDP1503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy.
- The cohort of patients with microsatellite stable colorectal cancer who had previously failed all therapies for metastatic disease is fully recruited. No clinical responses have been evident; however, several patients in this cohort have experienced extended stable disease. Cellular infiltration biomarker changes were also observed in tumor biopsies taken from those patients during the EDP1503 monotherapy period, which are consistent with preclinical observations for EDP1503. Evelo continues to monitor patients in this cohort.
- Given newly approved treatments for triple-negative breast cancer, Evelo anticipates that the majority of triple negative breast cancer patients to be recruited will have relapsed following prior PD-1/L1 therapy, similarly to those in the PD-1 relapsed cohort.
- Evelo expects to report further clinical data from this trial in the first half of 2020.

**Business Highlights**

- In September 2019, Evelo appointed David Epstein as chairman of its Board of Directors. Mr. Epstein, who has been a director of Evelo since March 2017, brings extensive experience and relationships in the biotech and pharmaceutical industries to his role as chairman. He currently serves as chairman of the Board of Directors of Rubius Therapeutics and Axcella Health and as a director at International Flavors and Fragrances. From January 2010 - July 2016, Mr. Epstein served as chief executive officer of Novartis Pharmaceuticals, a division of Novartis AG. In conjunction with Mr. Epstein's appointment, Noubar Afeyan, Ph.D., co-founder of Evelo and chief executive officer of Flagship Pioneering, stepped down from his role on Evelo's Board.

**Third Quarter 2019 Financial Results**

- **Cash Position:** As of September 30, 2019, cash and cash equivalents were $97.1 million, as compared to cash, cash equivalents and investments of $147.9 million as of December 31, 2018 and $113.5 million as of June 30, 2019. This decrease was due to cash used to fund operating activities and capital expenditures for the third quarter of 2019. Evelo expects that its cash and cash equivalents, together with funds available under tranche 2 of its debt facility, will enable it to fund its planned operating expenses and capital expenditure requirements to the end of 2020.
- **Research and Development Expenses:** R&D expenses were $15.6 million for the three months ended September 30, 2019, compared to $11.2 million for the three months ended September 30, 2018. The increase of $4.4 million was due primarily to increases in costs related to Evelo's inflammation clinical programs and research platform expenses, as well as increased personnel costs.
- **General and Administrative Expenses:** G&A expenses were $5.9 million for the three months ended September 30, 2019, compared to $5.2 million for the three months ended September 30, 2018. The increase of $0.7 million was due primarily to increased personnel costs to support Evelo's growth.
- **Net Loss:** Net loss attributable to common stockholders was $21.6 million for the three months ended September 30, 2019, or $0.67 per basic and diluted share, as compared to a net loss of $15.9 million for the three months ended September 30, 2018, or $0.50 per basic and diluted share.

**Conference Call**

Evelo will host a conference call and webcast at 8:30 a.m. EST today to review the new clinical data for EDP1815. To access the call please dial 866-795-3242 (domestic) or 409-937-8909 (international) and refer to conference ID 7788384. A live webcast of the event will also be available under "News and Events" in the Investors section of Evelo's website at http://ir.evelobio.com. The archived webcast will be available on Evelo's website approximately two hours after the completion of the event and will be available for 30 days following the call.

**About Evelo Biosciences**

Evelo Biosciences, Inc. is a clinical stage biotechnology company developing oral biologics that act on cells in the small intestine with systemic therapeutic effects. These cells in the small intestine play 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. They have been observed in pre-clinical models to have systemic dose-dependent effects, modulating multiple clinically validated pathways. 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 three product candidates, EDP1066 and EDP1815 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.

**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, EDP1066 and EDP1503, the timing and results of any clinical studies or readouts, and the sufficiency of cash to fund operations.*

*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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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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**Financial Tables**

**EVELO BIOSCIENCES, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**
**(in thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Operating Expenses(1): | | | | |
| Research and development | $ 15,610 | $ 11,227 | $ 46,751 | $ 28,542 |
| General and administrative | 5,886 | 5,230 | 16,936 | 13,568 |
| Total operating expenses | 21,496 | 16,457 | 63,687 | 42,110 |
| Loss from operations | (21,496) | (16,457) | (63,687) | (42,110) |
| Other income (expense), net | (137) | 600 | 814 | 607 |
| Net loss | $ (21,633) | $ (15,857) | $ (62,873) | $ (41,503) |
| Preferred stock dividends | — | — | — | (3,937) |
| Net loss attributable to common stockholders | $ (21,633) | $ (15,857) | $ (62,873) | $ (45,440) |
| Net loss per share - basic and diluted | $ (0.67) | $ (0.50) | $ (1.96) | $ (2.45) |
| Weighted-average common shares used in computing net loss per share - basic and diluted | 32,060,747 | 31,741,683 | 32,009,571 | 18,532,408 |

(1) Expenses include the following amount of non-cash stock-based compensation expense:

| | | | | |
|---|---|---|---|---|
| Research and development | $ 980 | $ 764 | $ 2,844 | $ 1,767 |
| General and administrative | 1,082 | 831 | 3,306 | 2,727 |

**EVELO BIOSCIENCES, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)**
**(in thousands)**

| | **September 30, 2019** | **December 31, 2018** |
|---|---|---|
| Assets: | | |
| Cash, cash equivalents and investments | $ 97,061 | $ 147,919 |
| Property and equipment, net | 8,339 | 6,925 |
| Other assets | 5,740 | 5,023 |
| Total assets | $ 111,140 | $ 159,867 |
| Liabilities and stockholders' equity: | | |

| | | |
|---|---|---|
| Accounts payable and current liabilities | $ 9,675 | $ 9,235 |
| Long-term debt | 19,549 | 12,305 |
| Other liabilities | 1,370 | 1,378 |
| Total liabilities | 30,594 | 22,918 |
| | | |
| Total stockholders' equity | 80,546 | 136,949 |
| Total liabilities and stockholders' equity | $ 111,140 | $ 159,867 |

Source: Evelo Biosciences, Inc.