# Pluristem Completes Interim Enrollment in Pivotal CLI Study, Targeting Potential Conditional Marketing Approval in Europe

**HAIFA, Israel, April 29, 2019 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced the Company has achieved a significant milestone in its ongoing development of PLX-PAD for the treatment of critical limb ischemia (CLI). The company has met its enrollment timelines relating to its Phase III pivotal study in CLI sooner than expected, and has successfully enrolled over 50% of the study's patients, which allows for an interim analysis of efficacy after a one-year follow-up period under the European Medicine Agency's (EMA) Adaptive Pathways pilot project, which PLX-PAD was selected for. The interim analysis, if positive, could support an application for conditional marketing approval, which could accelerate the approval and commercial availability of PLX-PAD in the Europe.

Pluristem also announced today the official initiation of its U.S. Food and Drug Administration (FDA)-approved Expanded Access Program (EAP), with several site initiations in the U.S. This program makes Pluristem's PLX-PAD cell therapy product available to CLI patients who are unsuitable for inclusion in the Company's ongoing multinational Phase III clinical study. The EAP will enroll up to 100 patients with Rutherford Category 5 CLI and provides Pluristem the opportunity to collect data while the global Phase III study is ongoing. Pluristem previously announced that it received approval from the FDA for cost recovery for patient treatments administered under the EAP.

"Pluristem's development program for its novel cell therapy, PLX-PAD, for the treatment of CLI continues to progress, and we are rapidly approaching a significant data milestone with a potential interim efficacy analysis that could expedite commercial availability in Europe," stated Zami Aberman, Chairman and Co-Chief Executive Officer of Pluristem. "We are pleased to see positive collaboration from our clinical sites, where we beat our expected timelines for patient enrollment. We will use the remaining year to prepare the company for its potential application for conditional marketing approval in Europe under the adaptive pathway designation. We look forward to conducting this interim analysis with the goal of making this promising therapy available to patients as quickly as possible."

"CLI is a devastating disease that can result in diminished quality of life and a high risk of amputation and death. With lack of suitable non-surgical therapeutic options for the growing

population of CLI patients, new approaches such as cell therapy are warranted. In multiple completed studies to date, PLX-PAD demonstrated significant improvement in reducing the risk for amputation and death, improved tissue perfusion and reduced ischemic pain, all while demonstrating a very favorable safety profile." Mr. Aberman concluded, "We are glad to receive the FDA's support for our EAP and are privileged to be able to provide PLX-PAD to patients in need, with the goal to prevent amputations and save lives."

The Phase III CLI program has been awarded a €7.6 million grant from the European Union's Horizon 2020 program, which is its largest EU research and innovation program. The collaborative project includes leading European research institutes and clinical sites, which undertake an extensive scientific program in parallel to the trial, using in-depth immunological, endocrine, and molecular analyses to better understand the mechanism of action of PLX-PAD in CLI.

In addition to the EMA's Adaptive Pathways program and the FDA's EAP, PLX-PAD has been granted FDA Fast Track Designation for the treatment of CLI.

**About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; a Company-owned and operated GMP-certified manufacturing and research facility; strategic relationships with major research institutions; and a seasoned management team.

**About Critical Limb Ischemia (CLI)**

Critical Limb Ischemia (CLI) is the most severe form of peripheral artery disease (PAD), a chronic illness in which blood flow to the limbs is obstructed. PAD is the most prevalent cardiovascular disease in the world, affecting more than 200 million people, and one of the most common chronic diseases in the U.S., surpassing even cancer. It is estimated that 5-6 million people in U.S. and Europe suffer from CLI with an estimated cost of 25 billion $ per year in the U.S. alone. With the increasing rate of aging and diabetes, this number is projected to grow in the coming years. Today, up to 40% of CLI patients are unsuitable for revascularization and experience up to 40% amputation rate at 1 year, left with no medical solution other than amputation.

**Safe Harbor Statement**

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example,

Pluristem is using forward-looking statements when it discusses that the interim analysis of the Phase III study, if positive, could support an application for conditional marketing approval, which could also accelerate the approval and commercial availability of PLX-PAD in the European Union, the enrollment of patients and the expected collecting of data in its EAP and the expected timing for the preparation of a potential application for conditional marketing approval in Europe under the adaptive pathway designation. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

**Contact:**
Efrat Kaduri
Director of Business, Investor and Public Relations
972-74-7108600
efratk@pluristem.com