



## Pluristem Completes 75% Enrollment in its Pivotal Phase III CLI Clinical Study

- **Patients unsuitable for revascularization surgery currently have no alternative treatments, leading to high risk of leg amputation and death; PLX-PAD may become the first drug approved to treat CLI**

**HAIFA, Israel, December 17, 2019** - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that it has enrolled 75% of the 246 patients planned for its Phase III clinical study of PLX-PAD in the treatment of Critical Limb Ischemia (CLI), the most severe form of peripheral artery disease, caused by fatty deposits in leg arteries obstructing blood flow.

While an estimated 5 to 6 million people in the U.S. and Europe suffer from CLI, up to 35% of patients are not eligible for the standard-of-care treatment of revascularization surgery. These patients are left with no treatment options and are at high risk of leg amputation and death. Incidence of CLI is increasing, driven by an aging population and a rise in risk factors, including diabetes and obesity.

PLX-PAD is among the most advanced drugs under development to treat CLI patients, with the goal to serve a large population for which there is a significant need for therapy. “We are pleased to be meeting our patient recruitment goals as we look forward to completing this pivotal study,” stated Pluristem President and CEO Yaky Yanay. “We aim to bring hope to millions of CLI patients around the world by delivering a regenerative treatment that can save limbs and lives while also saving costs for the healthcare systems. We are pleased to receive significant regulatory and financial support while developing such a novel therapy for CLI, including fast track designation from the U.S. Food and Drug Administration (FDA) and Adaptive Pathway designation from the European Medicine Agency (EMA) that may enable faster regulatory approvals. We understand the importance of a successful outcome in this study for the benefit of this large population of patients and for the benefit of all of our stakeholders. We at Pluristem are fully committed to deliver the first and leading drug for CLI patients across the globe.”

PLX-PAD has been selected for the EMA’s Adaptive Pathways pilot project, allowing for potential accelerated approval in Europe based on an interim analysis of half of the patients in the study. In the U.S., PLX-PAD was granted a fast track designation and was accepted to an expanded access program by the FDA. €7.6 million has been granted to Pluristem’s Phase III CLI program – the PACE study, from the European Union’s Horizon 2020 program, the largest EU research and innovation program. The Phase III randomized, double blind, placebo-controlled study is enrolling 246 CLI patients who are unsuitable for revascularization in over 50 sites across Europe, the U.S., and Israel. Patients are treated with two intramuscular treatments of 300 million cells of PLX-PAD or placebo, at a randomized ratio of 2:1. The primary efficacy endpoint is time to occurrence of a major leg amputation or death.

## **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.

## **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 the potential of its PLX-PAD to become the first and leading drug approved to treat CLI patients across the globe, that its PLX-PAD drug is being targeted to serve a large population for which there is a significant need for therapy, the potential of Pluristem and its study to deliver a regenerative treatment that can save limbs and lives while also saving costs for the healthcare systems and the potential for accelerated regulatory approvals in the U.S. and Europe. 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.

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