# Pluristem's Phase III Critical Limb Ischemia Study Wins $8 Million Grant from Europe's Horizon 2020 Program

- ***The study will enroll about 250 patients in Europe and the U.S.***
- ***The grant will cover a significant portion of the study expenses***
- ***PLX-PAD was previously selected by the EMA to be developed via the Adaptive Pathways project***

**HAIFA, ISRAEL, August 9, 2016 --** Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that its critical limb ischemia (CLI) program in the European Union has been awarded an $8 million grant. The grant is part of the European Union's Horizon 2020 program, which is its largest Research and Innovation program. The Phase III study of PLX-PAD in CLI will be a collaborative project carried out by an international consortium led by the Berlin-Brandenburg Center for Regenerative Therapies (BCRT) under the leadership of Prof. Hans-Dieter Volk and Prof. Petra Reinke together with Pluristem.

The consortium, which will include leading European research institutes and clinical sites, will 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.

As previously announced, Pluristem's PLX-PAD development program has been selected for the EU's Adaptive Pathways project, whose goal is to shorten the time it takes for innovative medicines to reach patients with serious conditions that lack adequate treatment options.

"We are honored to have been awarded this Horizon 2020 grant designed to support the manufacturing and development of our cell products for potential commercialization. This grant is a vote of confidence and an expression of hope by the European Union that we may be able to provide a regenerative therapy for millions of CLI patients around the world. Pluristem is committed to developing PLX-PAD for patients with peripheral artery disease, and this grant will help us move towards our goal of rapid entry into the European and U.S. markets, given positive results," stated Pluristem Chairman and CEO Zami Aberman.

The pivotal study for Pluristem's PLacental eXpanded (PLX) PAD cells in the treatment of CLI is a double blind, randomized, placebo controlled trial in an estimated 250 patients with CLI Rutherford Category 5 who are unsuitable candidates for revascularization. Patients will be treated

with 300 million cells or placebo, injected twice intramuscularly (IM), with the second dose administered two months after the first. The primary endpoint will be time to amputation and death.

Patients will be enrolled in clinical sites located throughout Europe and the U.S. Pluristem's intention is to utilize this study as a single pivotal trial for regulatory approval in both regions. PLX-PAD cells are designed to address the $12 billion global CLI market.

**About the Berlin-Brandenburg Center for Regenerative Therapies**

The Berlin-Brandenburg Center for Regenerative Therapies (BCRT) was founded as a cooperative research institution of the Charité University Hospital in Berlin, which is one of the largest university hospitals in Europe, and Germany's largest research association, the Helmholtz Association. The goal of the BCRT is to enhance endogenous regeneration by cells, biomaterials, and factors which can be used to develop and implement innovative therapies and products. The primary focus of the BCRT is on diseases of the immune system, the musculoskeletal system and the cardiovascular system for which currently only unsatisfactory treatment options are available.

**About the Adaptive Pathways**

The purpose of Europe's Adaptive Pathways is to shorten the time it takes for innovative medicines to reach patients with serious conditions that lack adequate treatment options. The pathway is open to clinical programs in early stages of development only. After a therapy is selected for the program, the Adaptive Pathways group conducts high level discussions and provides guidance to the applicant regarding the formal regulatory processes that precede a trial targeting early approval and further expansion of the indications.

**About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cells release a range of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has a strong intellectual property position; company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

**Safe Harbor Statement**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, forward-looking statements are used in this press release when we discuss obtaining the $8 million grant as a part of the EU's Horizon 2020 program, the estimated use of the grant, the potential for obtaining conditional marketing approval in Europe in the event of positive results of our pivotal CLI trial and Pluristem's intention to utilize the results of the CLI trial in applying for

regulatory approval in both the Europe and the U.S. 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; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; 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; our patents may not be sufficient; our products may harm recipients; changes in legislation; 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. 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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