Pluristem on Track to Proceed to a Phase II/III Clinical Trial in Critical Limb Ischemia (CLI) Under a Joint FDA-EMA Protocol, and a Phase II Clinical Trial in Intermittent Claudication (IC)

Haifa, Israel – January 18, 2011 (BUSINESS WIRE) – Pluristem Therapeutics, Inc. (NASDAQ:PSTI; TASE:PLTR), today announced the successful completion of a parallel scientific advisory process with the European Medical Agencies (EMA) and the U.S. Food and Drug Administration (FDA) regarding the Company's planned clinical development program for PLX-PAD.

Based on positive feedback from the EMA and FDA, Pluristem feels that it is now in a position to advance towards two clinical studies with its PLX-PAD cells: a joint FDA-EMA Phase II/III study of PLX-PAD for CLI and a Phase II study for IC under the FDA and the Paul Ehrlich Institute (PEI), the German competent authority in the European Union.

"PLX-PAD has shown promise throughout its initial clinical development, and I am pleased that both the EMA and FDA have acknowledged our proposed comprehensive clinical development plan, which may lead to an advanced cell therapy product that could help millions of PAD patients.

The completion of two Phase-I CLI clinical studies, performed in parallel in Germany and the U.S., placed Pluristem in a unique position to discuss with the regulatory agencies an approach that should allow a single clinical study protocol to be accepted by both agencies", commented Zami Aberman, Chairman and Chief Executive Officer of Pluristem.

"What is particularly exciting about this development," continued Aberman, "is that it places us – for the first time – on-track for a potentially preventative treatment for PAD in addition to treating amputation-destined cases."

"PLX-PAD has shown an early read-out of efficacy throughout its clinical development and I am pleased that PLX-PAD has made the necessary progress from a regulatory perspective, to move forward with advanced trials," commented Edwin Horwitz, MD, PhD, President of the International Society for Cell Therapy, and the head of Pluristem's scientific advisory board. "I am excited that the PLX-PAD clinical trials will be conducted in the EU and the U.S. under the same

clinical protocol, bringing the therapy closer to market and to those CLI patients in need of improved therapies."

The EMA and FDA concurred on the main protocol design elements. The Phase II/III clinical trial will be a multinational, multicenter, randomized, double-blind, placebo control, parallel study. Patients with CLI, Fontaine class III-IV, Rutherford category 4-5, will be enrolled and treated with two PLX-PAD treatments or with two placebo treatments, a few months apart. PLX-PAD or placebo will be administered via multi-intramuscular injections delivered to the affected leg.

The primary endpoint of the study will be major-amputation free survival rate (amputations and death) at 12 months from the initial treatment with PLX-PAD or placebo.

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About Pluristem

Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR) is a leading developer of placenta-based cell therapies. The company's patented PLX (PLacental eXpanded) cells drug delivery platform releases a cocktail of therapeutic proteins in response to a variety of local and systemic inflammatory diseases. PLX cells are grown using the company's proprietary 3D micro-environmental technology and are an off-the-shelf product that requires no tissue matching or immune-suppression treatment prior to administration. PLX-PAD comprehensive clinical development plan has been recognized by both the EMA and FDA, targeting a *sub-population of 20-million patients of* Peripheral Artery Disease (*PAD) market;*

Data from two Phase I clinical trials indicate that Pluristem's first PLX product, PLX-PAD, is safe and potentially effective for the treatment of end stage PAD. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in nerve pain and muscle damage when administered locally and in inflammatory bowel disease, MS and stroke when administered systemically.

Pluristem has a strong patent portfolio, company-owned GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned management team. For more information visit www.pluristem.com, the content of which is not part of this press release. Follow Pluristem on Twitter @Pluristem.

CLICK HERE to watch a video in which CLI patients and doctors involved with the clinical trials share their stories. CLICK HERE to see Pluristem's cell therapy product animation on YouTube.

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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, we are using forward looking statements when we say that we feel that we are now in a position to advance towards two clinical studies with our PLX-PAD cells under joint FDA-EMA Phase II/III study of PLX-PAD for CLI and a Phase II study for IC under the FDA and the Paul Ehrlich Institute (PEI); or that PLX-PAD has shown promise throughout its initial clinical development, and that both the EMA and FDA have acknowledged our proposed comprehensive clinical development plan, which may lead to an advanced cell therapy product that could help millions of PAD patients; or that the completion of two Phase-I CLI clinical trials, performed in parallel in Germany and the U.S., placed us in a unique position to discuss with the regulatory agencies an approach that should allow a single clinical study protocol to be accepted by both agencies; or that this development placed us on-track for a potentially preventative treatment for PAD in addition to treating amputation-destined cases; or that PLX-PAD has shown an early read-out of efficacy throughout its clinical development and has made the necessary progress from a regulatory perspective; or that the Phase II/III PLX-PAD clinical trials will be bringing the therapy closer to market and to those CLI patients in need of improved therapies; or that this Phase II/III clinical trial will be a multinational, multicenter, randomized, double-blind, placebo control, parallel study; that the primary endpoint of the study will be major-amputation free survival rate, or when we discuss the data from our two phase I clinical trials and pre-clinical animal models. These forward-looking statements 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 our clinical trials; 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 surgical settings; 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.