Pluristem Reaches Agreement with Japan's PMDA on Protocol for Final Trial Targeting Market Entry via Accelerated Pathway

- ***The agreement is expected to accelerate discussions with potential Japanese partners***
- ***The study will include 75 patients and a 9 month follow-up***

HAIFA, ISRAEL, December 21, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM / TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that it has reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on the design of the final trial needed to apply for conditional approval of PLX-PAD cells in the treatment of critical limb ischemia (CLI). The approval of the protocol for the 75-patient trial was part of a larger agreement on the development of PLX-PAD via Japan's new accelerated regulatory pathway for regenerative medicine.

"With this achievement we have advanced our strategy to expedite commercialization of our cell products. Pluristem is now positioned favorably to accelerate negotiations with those Japanese pharma companies interested in becoming dominant players in the expanding regenerative medicine market in Japan," stated Pluristem Chairman and CEO Zami Aberman.

The trial will collect data on 75 patients suffering from CLI. These patients will be randomized into three groups of 25. Group one will receive an initial 150 million PLX-PAD cell dose followed eight weeks later by a second 150 million cell dose; group two will be treated with an initial 300 million PLX-PAD cells followed eight weeks later by a second dose of 300 million cells; group three will receive two doses of placebo. The cells will be injected into a leg muscle using a standard syringe. Efficacy and safety will be determined from outcomes measured nine months after administration of the first dose. The primary efficacy endpoint will be diagnosis of a patient as CLI-free for 60 days. Pluristem expects to submit the formal Clinical Trial Notification (CTN) to the PDMA, based on the agreement reached with the regulatory body, in early 2016. The PMDA is expected to respond officially within 30 days. Earlier in 2015, the PMDA cleared PLX-PAD cells for use in clinical studies in Japan, a prerequisite to conducting this clinical trial.

About Japan's Conditional Time-limited Approval for Regenerative Medicines

Japan's Act on the Safety of Regenerative Medicines went into effect in November 2014. Its purpose is to facilitate faster approval of cellular therapies and other regenerative medicine treatments for marketing. According to the law, these therapies can receive conditional, time-limited approval for marketing, and be eligible for reimbursement, upon proof of safety and a signal of effectiveness but prior to verification of efficacy. Safety and efficacy need to be confirmed via collection of observational data after the conditional approval.

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 cocktail 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, 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, we are using forward-looking statements when we discuss our expectation that the agreement with the PDMA will accelerate discussions with potential Japanese partners, when we discuss our plan to conduct clinical trial of PLX-PAD cells in the treatment of CLI and the trial's design, and when we discuss our expectation to submit the formal CTN to the PDMA by the end of Q1, 2016 and the expected timing of response by the PDMA. 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.