Pluristem Receives Approval from Indian Ministry of Health for Use of PLX Cells in Phase II Trial for Treatment of Buerger's Disease

Last year U.S. FDA designated Pluristem's PLX cells orphan status for the treatment of Buerger's disease

HAIFA, ISRAEL, August 16, 2012 -- Pluristem Therapeutics, Inc. (NASDAQCM:PSTI; TASE:PLTR), a leading developer of placenta-based cell therapies, announced today that it has received permission from the Indian Ministry of Health to proceed with a Phase II clinical trial for the treatment of thromboangiitis obliterans (Buerger's disease). This Phase II trial will be potentially followed by a larger multi-national Phase III study in the U.S., Europe and India.

Buerger's Disease is highly prevalent in India, affecting approximately 45% to 63% of the patients who have peripheral artery disease (PAD). The prevalence in India is particularly high among smokers. PAD afflicts an estimated 20 million people in India, which translates into approximately 11 million Indians suffering from Buerger's disease. As there are no established treatments available, there is a strong medical need – and therefore a significant market – for the development of therapeutics for this indication.

Last August, the U.S. Food and Drug Administration (FDA) designated Pluristem's PLX cells orphan status for the treatment of Buerger's disease, a severe disease affecting the blood vessels of the extremities. The disease is a recurrent, progressive inflammation and clotting of the small and medium arteries and veins of the hands and feet. Severe pain and ulcers of the extremities may occur, which may lead to amputation.

"We are very excited to begin this Phase II study for the treatment of Buerger's Disease in India," said Zami Aberman, Chairman, President and CEO of Pluristem. "The information gathered in this trial will be a valuable step towards our goal of successfully developing a PLX cell-based product for the treatment of the entire spectrum of peripheral vascular diseases."

About Pluristem Therapeutics

Pluristem Therapeutics Inc. (NASDAQCM: PSTI; TASE: PLTR) is a leading developer of standardized cell therapy products for the treatment of life threatening diseases. The

company's patented PLX (PLacental eXpanded) cells drug delivery platform releases a cocktail of therapeutic proteins in response to a host 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 prior to administration. Data from two phase I studies indicate that Pluristem's first PLX product candidate, PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease. 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, GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned management team.

For more information visit www.pluristem.com, or follow us on Twitter @Pluristem, the contents of which are not part of this press release.

CLICK HERE to watch a video where CLI patients and doctors involved with the clinical trials share their stories. , the content of which is not part of this press release.

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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 the Phase II trial referred to in this press release will be potentially followed by a larger multi-national Phase III study in the U.S., Europe and India, or when we imply that there will be a strong medical need and significant market for therapeutics for Buerger's disease, when we say that the information gathered in the Phase II trial in India will be a valuable step towards our goal of successfully developing a PLX cell-based product for the treatment of the entire spectrum of peripheral vascular diseases, when we say that data from two phase I studies indicate that PLX-PAD is safe and potentially effective, or when we discuss how pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic and other indications.. 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 or commercialize 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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