Pluristem Files for Orphan Drug Status with U.S. FDA for Use of PLX Cells in Treatment of Aplastic Anemia

Pluristem to establish Board of Key Opinion Leaders in Bone Marrow Transplants

HAIFA, ISRAEL, August 30, 2012 -- Pluristem Therapeutics, Inc. (NASDAQCM:PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced that it has filed the necessary documents requesting that the U.S. Food and Drug Administration (FDA) grant orphan drug status to its PLacental eXpanded (PLX) cells for the treatment of aplastic anemia.

The filing marks Pluristem's second orphan drug application to the U.S. FDA. The company applied once before, and successfully received in August of 2011, orphan drug status from the FDA for its PLX cell therapy in the treatment of Buerger's disease.

Aplastic anemia is a rare but serious disorder caused by destruction of blood-forming stem cells (Hematopoietic Stem Cells or HSCs) in the bone marrow. While normally HSCs develop into three types of blood cells, red blood cells, white blood cells and platelets, in aplastic anemia all blood types are deficient, a condition also known as pancytopenia. The disease is considered an emergency situation where patients are supported either with blood transfusions in anticipation of a bone marrow transplant (BMT) or with drugs that suppress the immune system. Aplastic anemia patients are included in the bone marrow transplant market estimated at $1.3 billion per year in the U.S. alone.

In May of this year, Pluristem announced that a seven year-old girl in Israel, whose condition was rapidly deteriorating due to aplastic bone marrow, experienced a reversal of her condition with a significant increase in her red blood cells, white blood cells and platelets following the intramuscular injection of the company's PLX cells. Prior bone marrow transplants had failed. The patient has subsequently been released from the hospital and returned home.

"The tremendous recovery exhibited by the pediatric patient afflicted with aplastic anemia who was given our PLX cells under compassionate use has prompted Pluristem to aggressively work towards quickly making our cells available for these patients, a process that will be expedited with the granting of orphan drug status," said Zami Aberman, Chairman and CEO of Pluristem. "We are now in the process of establishing an advisory board made up of key opinion leaders in the area of bone marrow transplantation from the United States, Europe and Israel to provide us with valuable insight as we expand our activities in the treatment of the bone marrow diseases and transplantations."

About Orphan Drug Status

Orphan drug designation qualifies a company for several benefits under the Orphan Drug Act of

1983 (ODA), as amended. These benefits include a 7-year period of orphan drug exclusivity upon product approval, a tax credit for certain clinical testing expenses for the orphan drug, written guidance on the non-clinical and clinical studies needed to obtain marketing approval of an orphan drug, and orphan drug grants.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. (NASDAQCM: PSTI) (TASE:PLTR) is a leading developer of placenta-based cell therapies. The Company's patented PLX (PLacental eXpanded) cells are a drug delivery platform that releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory and ischemic 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. Pluristem is focusing on the development of PLX cells administered locally to potentially treat systemic diseases and potentially obviating the need to use the intravenous route.

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 when given locally. Additionally, Pluristem is developing PLX-PAD for cardiac ischemia, PLX-BMP for Acute Radiation Exposure, Bone Marrow Transplant Failure and chemotherapy- induced Bone Marrow Aplasia, PLX-ORTHO for orthopedic indications and PLX-PAH for Pulmonary Hypertension in collaboration with United Therapeutics. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis.

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

The Pluristem Therapeutics Inc. logo is available at
http://www.globenewswire.com/newsroom/prs/?pkgid=6882

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, when we discuss how our work to make our cells available for patients will be expedited with the granting of orphan drug status, when we discuss the establishment of an advisory board, when we discuss that data from two phase I studies indicate that our PLX-PAD is safe and potentially effective for the treatment of end stage peripheral artery disease, or when we discuss how pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, we are using forward-looking statements. 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; 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.

Contact:
Pluristem Therapeutics Inc.:

William Prather R.Ph., M.D. Sr. VP Corporate Development
1-303-883-4954
William.PratherMD@pluristem.com

Daya Lettvin
Investor & Media Relations Director
+972-54-674-5580
daya@pluristem.com

Media Contact:
Matthew Krieger
Finn Partners – for Pluristem
+972-54-467-6950
matthew@finnpartners.co.il