



HAIFA, ISRAEL, August 25, 2011 -- [Pluristem Therapeutics, Inc.](#) (NASDAQ:PSTI; TASE:PLTR) today announced that on August 22, 2011 the U.S. Food and Drug Administration (FDA) designated Pluristem's PLX cells orphan status for the treatment of thromboangiitis obliterans (Buerger's disease). The Company also announced that a concurrent application in Europe at the EMA's Committee for Orphan Medicinal Products is pending.

Buerger's Disease, or thromboangiitis obliterans, is a rare and severe disease affecting the blood vessels of the extremities. It is characterized by inflammation and clotting of the vessels that result in a reduced blood flow to these areas. Severe pain and ulcers or necrosis of the extremities may occur, which may lead to amputation.

Buerger's Disease affects approximately 50,000 patients in the United States and Europe. As there are no established treatments available, there is a strong medical need for the development of drugs for this indication. Various sources estimate the market for the treatment of Buerger's disease to be approximately \$2.5 billion.

Zami Aberman, Chairman, President and CEO of Pluristem commented, "We are extremely pleased that our PLX cells have been designated orphan status by the FDA and look forward to receiving a similar designation in Europe. In anticipation of this designation, we have been working diligently in readying clinical sites, primarily in India, where there is a high prevalence of Buerger's. In addition, the inclusion of Buerger's completes our plan to make our PLX cells available for the entire spectrum of peripheral vascular disorders and allows us to benefit from the market exclusivity and other regulatory and financial advantages that accompany this designation."

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 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](https://twitter.com/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. [CLICK HERE](#) to see Pluristem's cell therapy product animation on YouTube.