

# United Therapeutics Advances to Second Cohort in Phase I Trial of Pluristem's PLX-PAD Cells for Treatment of Pulmonary Arterial Hypertension

HAIFA, ISRAEL, September 08, 2014 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR), a leading developer of placenta-based cell therapy products, announced today that its licensee, United Therapeutics Corporation, has completed the dosing of the first cohort of patients in its Phase I study using Pluristem's PLacental eXpanded (PLX-PAD) cells in patients diagnosed with pulmonary arterial hypertension (PAH). PAH, with a global market estimated at approximately \$3 billion, is characterized by abnormally high blood pressure in the arteries of the lungs; it can disrupt lung and heart function, leading to debilitating conditions such as heart failure.

The Phase I study, being conducted in Australia, is an open-label, dose-escalation study designed to enroll 9 patients diagnosed with PAH. The first cohort of 3 patients has received 0.5 million PLX cells per kilogram body weight. An independent Data Safety Monitoring Board recommended advancement to the second cohort. The second cohort will receive 1 million cells per kilogram, while the third cohort is planned to be administered 2 million cells per kilogram. The primary endpoint of the study is the safety of PLX-PAD cells, which will be evaluated at 12 weeks and one year after dosing. Secondary efficacy endpoints are to be measured at six weeks post-treatment in order to assess changes in the ability to exercise, disease severity and cardio-respiratory function; measures include six-minute walk distance and cardio-pulmonary hemodynamic parameters evaluated via right heart catheterization and echocardiogram.

"We look forward to preliminary results for this trial in 2015, after completion of dosing in all three cohorts," stated Pluristem Chairman and CEO Zami Aberman. "This Phase I study is important to the development of our PAH program in conjunction with United Therapeutics, and we are delighted to work with United Therapeutics in advancing the promise of cell therapy to treat pulmonary diseases."

The Phase I study is being conducted as part of a 2011 licensing agreement between United Therapeutics and Pluristem. Pursuant to the agreement, United Therapeutics will develop, market and sell Pluristem's PLX-PAD cells for PAH. Pluristem is eligible to receive up to \$55 million based on successful achievement of clinical milestones and commercialization, and reimbursement of certain R&D costs. Following

commercialization, United Therapeutics will purchase commercial supplies of PLX-PAD cells from Pluristem at a specified margin over Pluristem's cost, and will pay royalties at a percentage of its gross profits.

## **About Pulmonary Arterial Hypertension**

PAH is characterized by abnormally high blood pressure in the arteries of the lungs which leads to an increased workload on the right side of the heart; this can lead to heart failure and other negative health outcomes. It is a serious illness that becomes progressively worse and is sometimes fatal. PAH isn't curable, although treatments are available that can help lessen symptoms and improve quality of life.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company's patented PLX (PLacental eXpanded) cells are a protein delivery platform that releases a cocktail of therapeutic proteins in response to inflammation or ischemia. 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 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. For more information visit <a href="https://www.pluristem.com">www.pluristem.com</a>, the content of which is not part of this press release.

#### **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. Forward-looking statements include statements about future progress and completion of the Phase 1 study of PLX-PAD in PAH patients, milestone payments based on further clinical development, the possible commercialization of PLX-PAD by United Therapeutics and royalty payments and supply arrangements upon commercialization. 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 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.

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