



## **United Therapeutics Receives Regulatory Approval to Commence Phase I Study of Pluristem's PLX-PAD Cells for Pulmonary Arterial Hypertension**

HAIFA, Israel April 11, 2013 -- Pluristem Therapeutics Inc. (NASDAQCM: [PSTI](#)) (TASE:PLTR), a leading developer of placenta-based cell therapies, announced today that following favorable preclinical studies, United Therapeutics Corporation received approval to perform a human Phase I study in Australia using Pluristem's PLacental eXpanded (PLX-PAD) cells in patients diagnosed with Pulmonary Arterial Hypertension (PAH). On [June 20, 2011](#) United Therapeutics and Pluristem entered into a licensing agreement pursuant to which United Therapeutics will develop, market and sell Pluristem's PLX-PAD cells for PAH.

PAH is characterized by abnormally high blood pressure in the arteries of the lungs and leads to an increased workload on the right side of the heart.

United Therapeutics plans to conduct a single center, open-label, dose-escalation study in patients diagnosed with PAH. The study will enroll up to nine patients in three dosing levels with PLX-PAD cells administered intravenously (IV). The primary endpoint of the study is to evaluate the safety of PLX-PAD cells in a follow-up period of one year. Secondary efficacy endpoints at six weeks post-treatment are designed to assess cardio-respiratory function and include six-minute walk distance, cardiac hemodynamic parameters via a right heart catheterization and echocardiogram and pulmonary metabolism via a positron emission tomography (PET) scan.

Zami Aberman, Chairman and Chief Executive Officer of Pluristem Therapeutics stated, "We are very pleased with the progress of the project, moving our partnership with United Therapeutics to the next step. The in-vitro and pre-clinical development studies demonstrated that the administration of PLX-PAD cells appears to be safe and potentially effective in animal models of PAH. We are now looking forward to receiving clinical data from this trial in evaluating the safety of our PLX-PAD cell in treating PAH patients."

Under the terms of Pluristem's licensing agreement with United Therapeutics Corporation, United Therapeutics made an upfront payment of \$7 million to Pluristem. Pluristem is also eligible to receive regulatory milestone and other payments totaling up

to an additional \$48 million with United Therapeutics bearing all the costs of conducting all of the clinical trials for the indication of PAH. The licensing agreement also provides that, following commercialization, United Therapeutics will purchase the PLX-PAD cell product from Pluristem at a specified margin over Pluristem's cost. In addition, United Therapeutics will pay Pluristem specified royalties as a percentage of its gross profits generated from the sale of the PLX-PAD cell developed product.

Preclinical studies to evaluate the hemodynamic effects from the IV administration of PLX-PAD cells in the monocrotaline (MCT) rat model of PAH have been performed. These studies demonstrated that PLX-PAD cell treatment can lead to improvements in right ventricular systolic pressure (RVSP) compared to placebo-treated animals. Some treatment groups also demonstrated an improvement in right ventricular hypertrophy (RVH) as compared to placebo-treated animals.

#### **About United Therapeutics**

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening diseases.

#### **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.

Pluristem has a strong patent and patent applications 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](http://www.pluristem.com), 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. For example, we are using forward-looking statements when (a) we discuss the planned study in patients diagnosed with PAH, (b) we discuss the safety of PLX-PAD in treating PAH patients, and (c) we discuss future milestone-based payments, royalty payments and purchase of PLX-PAD cells for the indication of PAH, by United Therapeutics. 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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