Pluristem and United Therapeutics End Licensing Agreement; Report Positive Data in Pulmonary Arterial Hypertension

- ***Clinical study is ongoing and encouraging data reported for the first cohort***
- ***Pluristem regains full rights with benefit of human clinical data for the indication & IV administration of PLX cells***

HAIFA, ISRAEL, December 8, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM / TASE: PSTI), a leading developer of placenta-based cell therapy products, announced that it received a notice today from United Therapeutics Corporation ("United") ending its licensing agreement for the development of PLX-PAD for the treatment of pulmonary arterial hypertension (PAH). According to the licensing agreement Pluristem will regain full rights to PLX-PAD in this indication, as well as all clinical data and regulatory submissions, allowing Pluristem to move forward with the clinical development of the program and seek other licensing partners.

Data from the first cohort of three patients given PLX-PAD in the single-arm Phase I trial conducted by United in September 2014 which has now become available for publication, demonstrated a good safety profile and encouraging, albeit limited, efficacy trend. In addition, initial findings from cohort 1 suggest an average improvement of 21 meters from base line in the six-minute walk distance (6MWD) at 3-month follow up. The two patients with Grade 2 (moderate) PAH had an average improvement of 40 meters in 6MWD. The first cohort of patients received a single IV injection of 0.5 million cells/kg patient weight. Enrollment of the second cohort of patients is complete and follow up is ongoing. Those patients received 1 million cells/kg patient weight.

"We thank United for the work they have completed on this project and believe PLX-PAD can make a significant contribution to the health of patients suffering from PAH. The data generated by United provides a good foundation to suggest that our cells can be safely administered intravenously, with potential broad application, and can improve the quality of life for PAH patients. We have previously announced results from several studies that demonstrate the safety of intramuscular administration, and with the new intravenous data we can now expand the potential indications for which PLX cells can be used," stated Pluristem Chairman and CEO Zami Aberman.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring 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.

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 discuss our plans to move forward with the clinical development of the PLX-PAD for treatment of PAH program and seek other licensing partners, when we discuss PLX-PAD's potential to make a significant contribution to the health of patients suffering from PAH, when we discuss the potential for intravenous use of PLX cells across a broad range of indications, 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 clinical 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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