



Pluristem Announces Clearance to Move Forward with Enrollment for Cohort II in an Investigator-Led Phase I/II Chronic Graft vs Host Disease Study

Reports internal efficacy and safety data from first cohort

HAIFA, Israel, October 13, 2020 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological products, today announced that it has received clearance from the safety committee of an investigator initiated Phase I/II study to move forward with patient enrollment for cohort II. The study will evaluate PLX-PAD cells in the treatment of steroid-refractory chronic graft vs. host disease (GvHD) and is led by Principal Investigator Prof. Ron Ram, Director of the Hematology Blood and Marrow Stem Cell Transplantation Unit at Tel Aviv Sourasky Medical Center, Ichilov Hospital, Israel. Prof. Ram and his research staff are responsible for the design and implementation of the study at Sourasky Medical Center.

GvHD is a severe complication in patients who have undergone an allogeneic hematopoietic cell transplantation (HCT) and is a major cause of morbidity and mortality in these patients in which the donated stem cells identify the recipient's body as foreign and attack it. The chronic form of GvHD (cGvHD) usually appears later than 100 days post-transplant.

Cohort I included 6 patients treated with 2 injections of 150 million cells, a week apart. At the 3-month follow up, interim safety results concluded that PLX-PAD cells were safe and that no treatment related side effects were reported. Efficacy results demonstrated that 4 out of the 6 patients reported improvement in symptoms that translated into a reduction in the severity of cGvHD with notable reduction in the required steroid doses for part of the patients. Based on these results, the study was approved to commence enrollment of 14 patients in cohort II to be treated with 4 injections of 150 million cells.

Prof. Ram of Ichilov Hospital commented, "From our experience in having treated 6 patients in the study to date, we have so far found no negative side effects from the use of the PLX-PAD cells in the treatment of steroid-refractory cGvHD. Patients with significant GvHD skin disorders previously unresponsive to multiple types of therapy showed remarkable response. Responses were also observed for severe mouth ulcers which prevented patients from eating solid foods. This resulted in a major improvement of quality of life and tapering of steroid doses."

“Pluristem is committed to contributing to the wellbeing and quality of life of our patients. cGvHD is an indication where we see a significant need to enhance the current course of treatment for this life-threatening condition among patients undergoing bone marrow transplants. The preliminary results from cohort I of this Phase I/II study, and prior preclinical data, both indicate that PLX-PAD cells may potentially treat cGvHD patients and mitigate symptoms. We are very pleased to cooperate with Prof. Ram and Sourasky Medical Center, and we place a high importance in examining PLX-PAD for this indication,” stated Pluristem CEO and President, Yaky Yanay.

About cGvHD

Chronic graft-versus-host disease (cGvHD) remains a common and potentially life-threatening complication of allogeneic hematopoietic stem cell transplantation (HCT). The 2-year cumulative incidence of chronic GvHD requiring systemic treatment is ~30% to 40% by National Institutes of Health criteria¹. The hematopoietic stem cell transplants are used to treat bone marrow failure resulting from treatment of some blood or bone marrow cancers as well as other hematologic failures, such as aplastic anemia, which are not related to cancer. The donated cells identify the recipient’s body as foreign and attack it as a result. While acute GvHD usually appears in the first 100 days after a transplant, and in specific body systems, chronic GvHD can occur at any time (even several years) after a transplant, and may manifest in many parts of the body such as: skin, mouth, eyes, liver, intestines, lungs and joints. Long term immunosuppression is given to try to prevent or treat cGvHD. Since this treatment suppresses the immune system for a very long time, patients are at high risk of infections, and are prescribed multiple medications to try to address this major risk.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; a Company-owned and operated GMP-certified manufacturing and research facility; strategic relationships with major research institutions; and a seasoned management team.

¹ Flowers ME, Martin PJ. How we treat chronic graft-versus-host disease. *Blood*. 2015 Jan 22;125(4):606-15. doi: 10.1182/blood-2014-08-551994. Epub 2014 Nov 14. PMID: 25398933; PMCID: PMC4304105., <https://pubmed.ncbi.nlm.nih.gov/25398933/>

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses the patient enrollment for cohort II for its Phase I/II study of its PLX-PAD cells, the implication from the results of the first patient cohort in the study, the belief that GvHD is an indication that has a significant need for enhanced treatments among patients undergoing bone marrow transplants and that the preliminary results from cohort I of the study, and the prior preclinical data, indicate that PLX-PAD cells may potentially treat chronic GvHD patients and mitigate symptoms. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; 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; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; 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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