Pluristem Initiates Two Pivotal Phase III Studies in Israel

Numerous Clinical Sites in Israel to join sites in the U.S. and Europe for Pivotal Phase III Studies of PLX-PAD Cell Therapy in the Treatment of Critical Limb Ischemia and Muscle Injury Following Hip Fracture

HAIFA, Israel, August 8, 2018 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, announced today that Israel's Ministry of Health has cleared the Company to commence patient recruitment in Israel for two ongoing pivotal Phase III trials of PLX-PAD cell therapy, one for the treatment of Critical Limb Ischemia (CLI) and another for the treatment of muscle injury following hip fracture surgery. Both trials have been accepted to accelerated approval pathways and have received a total of $16.7 million in grants from the European Union's Horizon 2020 Program.

"We are pleased to open clinical sites in Israel for both of our ongoing pivotal Phase III studies. These sites may enable Pluristem to apply for marketing approval in Israel for both indications, aligning with potential regulatory approvals in the U.S. and Europe and expedite the completion of recruitment of both pivotal trials," stated Pluristem Chairman and Co-CEO, Zami Aberman.

Pluristem's pivotal Phase III study of PLX-PAD cells in the treatment of CLI, which has received an $8 million grant from the European Union's Horizon 2020 program, and is currently recruiting patients in the U.S., U.K., Germany, Poland, Czech Republic, Hungary, Bulgaria and Macedonia. PLX-PAD has received the U.S. Food and Drug Administration's (FDA) Fast Track designation for the treatment of CLI and has been included in the European Medicines Agency (EMA) Adaptive Pathways program, which may lead to early conditional marketing authorization based on an interim analysis following treatment of half of the total 246 patients to be enrolled in the study. The FDA recently cleared PLX-PAD for its Expanded Access Program (EAP) for the treatment of patients with CLI who are not eligible for Pluristem's Phase III study. EAP allows the use of an investigational medical product outside of clinical trials and is usually granted in cases where patients are unsuitable for inclusion under the study protocol and the patient's condition is life-threatening with an unmet medical need.

Pluristem's pivotal Phase III study in the treatment of muscle injury following arthroplasty for hip fracture was awarded an $8.7 million grant by the European Horizon 2020 Program. This study will recruit 240 patients through clinical sites in the U.S., Europe and Israel.

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 cells and is entering late-stage trials in several indications. PLX cell products 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; Company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

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 its intent to apply for marketing approval for CLI and treatment of muscle injury following hip fracture surgery, the potential for Pluristem to obtain early conditional marketing authorization from the FDA and EMA relating to its PLX-PAD cells and its description of the recruitment and timing of its studies. 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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