

# \$8.7 Million Awarded to Support Phase III Femoral Neck Fracture Trial by EU Horizon 2020 Program

- With funding now in place Pluristem plans to launch a multinational Phase III in U.S. and Europe
- Total of \$16.7 Million (15 million Euro) in non-dilutive funding have been awarded from the Horizon 2020 program to fund clinical and research costs for PLX-PAD

HAIFA, ISRAEL, September 05 2017-- Pluristem Therapeutics Inc. (NASDAQ: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that its Phase III study of PLX-PAD cells to support recovery following surgery for femoral neck fracture has been awarded an \$8.7 million (7.4 million Euro) non-dilutive grant from the Horizon 2020 program, the European Union's largest research and innovation program. Final approval of the grant is subject to the finalization of the consortium and Horizon 2020 grant agreements. This marks the second grant awarded to a Pluristem Phase III trial by Horizon 2020, following an \$8 million (7.6 million Euro) award\_for its ongoing Phase III study of PLX-PAD cells in the treatment of Critical Limb Ischemia (CLI), which was awarded in August 2016.

The Phase III trial of PLX-PAD cells in the treatment of femoral neck fracture will be a collaborative effort between Pluristem and an international consortium led by the Charité – Universitätsmedizin Berlin, under the leadership of Dr. Tobias Winkler, Principal Investigator at the Berlin-Brandenburg Center for Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery. Dr. Winkler also served as Senior Scientist for Pluristem's completed Phase I/II study of PLX-PAD for hip surgery. That trial demonstrated that patients treated with Pluristem's PLX-PAD cells during total hip arthroplasty experienced significant muscle regeneration compared to the control group with an improvement in muscle force and in muscle volume six months after surgery.

Dr. Winkler commented, "Following the impressive results from the Phase I/II study of PLX-PAD cells in a similar orthopedic indication, we are excited to advance PLX-PAD cell therapy into a Phase III study to aid in muscle regeneration in patients recovering from femoral neck fracture. If similar results are achieved in this Phase III trial, it could show that PLX-PAD cells can improve outcomes in these procedures and change the way recovery is managed worldwide."

Femoral neck fracture is the most common form of hip fracture, with mortality rates of up to 36%, and annual treatment costs estimated to be between \$10-\$15 billion in the U.S. alone. The number of surgeries performed annually to treat femoral neck fractures is increasing as populations age. Following surgery, many patients do not regain their baseline capabilities due to

poor muscle healing and regeneration, which leads to significantly increased morbidity and a lower quality of life.

"We are honored to receive this second grant from the Horizon 2020 program," stated Pluristem Chairman and Co-CEO Zami Aberman. "We believe this grant reflects a vote of confidence by the European Union and signals the need for cell therapy solutions to enable patients to lead healthier lives and to relieve health systems' financial burdens. We are confident that this grant will help us move towards rapid entry into the European and U.S. markets."

Pluristem's PLX-PAD program is one of only a handful to be accepted into Europe's Adaptive Pathway program, the purpose of which is to shorten the time it takes for innovative medicines to reach patients with serious conditions that lack adequate treatment options. Pluristem plans to enroll patients at clinical sites throughout Europe and the U.S. The study is expected to serve as a pivotal trial for regulatory approval in both regions.

# **About the Berlin-Brandenburg Center for Regenerative Therapies**

The Berlin-Brandenburg Center for Regenerative Therapies (BCRT) was founded as a cooperative research institution of the Charité University Hospital in Berlin, which is one of the largest university hospitals in Europe, and Germany's largest research association, the Helmholtz Association. The goal of the BCRT is to enhance endogenous regeneration by cells, biomaterials, and factors which can be used to develop and implement innovative therapies and products. The primary focus of the BCRT is on diseases of the immune system, the musculoskeletal system and the cardiovascular system for which currently only unsatisfactory treatment options are available.

#### **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, 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 its discusses the Phase III Studies of PLX-PAD cells and possible results, that the final approval of the Horizon 2020 grant is subject to finalizing the consortium and Horizon 2020 grant agreements, that Pluristem believes the grant is a vote of confidence by the European Union and signals the need for cell therapy solutions to enable patients to lead healthier lives and to relieve health systems' financial burdens, when Pluristem

states it is confident that the grant will help it move towards rapid entry into the European and U.S. markets and that the Phase III femoral neck fracture study is expected to serve as a pivotal trial for regulatory approval in the European Union and the U.S. 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 forwardlooking 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.

## Contact:

Karine Kleinhaus, MD, MPH Divisional VP, North America 1-914-512-4109 karinek@pluristem.com

Efrat Kaduri Head of Investor and Public Relations 972-74-7108600 efratk@pluristem.com