



## **Pluristem Receives Positive Feedback from FDA and EMA as Company Prepares for Phase III Trial of PLX-PAD to Support Recovery from Hip Fracture**

- *Trial was recently awarded \$8.7 million grant from the European Horizon 2020 program*
- *Pluristem plans to use results of trial to achieve marketing approval in both the U.S and Europe*

**HAIFA, ISRAEL, September 26, 2017**-- [Pluristem Therapeutics Inc.](#) (NASDAQ: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, has today reported the status of its planned Phase III hip fracture study. In previous discussions held with the U.S. Food and Drug Administration (FDA) and the European Medicine Agency (EMA), the company received positive feedback on the proposed study design and endpoints of its Phase III trial in PLX-PAD cells as a treatment for muscle recovery following arthroplasty for hip fracture. This trial was recently awarded an \$8.7 million grant by the Horizon 2020 program, the European Union's largest research and innovation program.

The proposed Phase III trial is intended to support marketing authorization and will be a double-blind, randomized, placebo-controlled trial with approximately 180 patients enrolled in clinical sites across the U.S. and Europe. Patients will be injected intramuscularly with 150 million PLX-PAD cells during arthroplasty for hip fracture. The primary endpoint for the trial will be the change of Short Physical Performance Battery (SPPB) from baseline to six months after surgery. Additional endpoints may include objective measurements of muscle strength and muscle volume.

This Phase III trial follows positive [results](#) from a Phase I/II trial which demonstrated significant muscle regeneration when PLX-PAD cells were injected following arthroplasty, including a 300% improvement in muscle volume ( $p=0.004$ ) and a 500% ( $p=0.0067$ ) boost in muscle force when observed six months after surgery compared to the control group.

"Now that this Phase III trial has been awarded \$8.7 million from the Horizon program, we are eager to move forward and are extremely pleased by the positive outlook of these key regulatory bodies regarding our proposed study design and endpoints, which we believe may allow for early recognition of performance improvement in patients," noted Zami Aberman, Chairman and Co-CEO of Pluristem. "With this positive feedback from the FDA and EMA, we believe that this trial will again yield significant results, offering new hope for the thousands of patients around the world who have difficulty healing from hip surgeries due to poor muscle recovery."

Pluristem plans to submit the Investigational New Drug (IND) and Clinical Trial Application (CTA) for the trial in the coming months. The company plans to use the results of this Phase III trial to achieve regulatory

approval in both the U.S and Europe. Pluristem's PLX-PAD program is one of only a handful to be accepted into Europe's Adaptive Pathway program, which may also allow for early marketing approval in Europe.

### **About Hip Fracture**

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. Following surgery, many patients do not fully recover due to poor muscle regeneration, leading to significant morbidity, loss of the ability to live independently, and an overall decline in quality of life. The incidence of hip fracture is expected to increase as populations age.

### **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 it discusses the timing and format of the proposed Phase III study, that the proposed Phase III trial is intended to support marketing authorization, that the proposed endpoints of the proposed Phase III trial may allow for early recognition of performance improvement in patients, that Pluristem believes that the proposed Phase III trial will yield significant results, that Pluristem plans to submit the IND and CTA for the proposed Phase III trial in the coming months and that Pluristem plans to use the results of the proposed Phase III trial to achieve regulatory approval in both the U.S. and Europe. 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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