Pluristem Granted Key U.S. Patent for Skeletal Muscle Regeneration - a Meaningful Asset Ahead of Upcoming Phase III Femoral Neck Fracture Study

- Patent relates to the use of Mesenchymal Stem Cells (MSCs) for muscle regeneration following muscle injury
- Pivotal Phase III study to take place in U.S. and Europe to support recovery from hip fracture

HAIFA, ISRAEL, November 22, 2017-- Pluristem Therapeutics Inc. (NASDAQ: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that the U.S. Patent and Trademark Office (USPTO) has issued a patent titled, “Skeletal muscle regeneration using mesenchymal system cells.” This key patent, which has already been granted in Europe, Hong Kong and Israel, addresses the use of MSCs for skeletal muscle regeneration used either directly after, or shortly after, post-surgical muscle injury.

The Company received positive feedback from the U.S. Food and Drug Administration (FDA) and the European Medicine Agency (EMA) for the proposed study design and endpoints of its Phase III trial for the treatment of muscle recovery following arthroplasty for hip fracture. This planned study was recently awarded an $8.7 million grant by the Horizon 2020 program, the European Union’s largest research and innovation program. If successful, Pluristem plans to use the study results to achieve marketing approval in both the U.S. and Europe.

Previous clinical studies using PLX-PAD cells demonstrated significant muscle regeneration 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.

“This very important patent comes at the right time, just ahead of our planned Phase III study in muscle regeneration following hip fracture,” stated Zami Aberman, Chairman and Co-CEO of Pluristem. “The patent substantially strengthens our intellectual property around muscle regeneration, particularly as it pertains to repair and regeneration following surgery. In an industry that demands constant technological and scientific advances, a robust patent portfolio covering our core innovations strengthens Pluristem’s competitive edge.”

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 positive feedback it received from regulatory authorities and the potential that such feedback will result in approval to conduct clinical trials, the actual receipt of grants, the initiation and successful completion of planned clinical trials, the potential to receive marketing approval for Pluristem’s products and the potential of the patent reported above to and other intellectual property rights Pluristem owns to support Pluristem’s competitive edge. 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.

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