

# Pluristem Therapeutics Reports Fiscal 2019 First Quarter Results and Provides Corporate Update

HAIFA, Israel, November 8, 2018 - <u>Pluristem Therapeutics Inc.</u> (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today reported financial results for its fiscal first quarter 2019 ended September 30, 2018 and provided a corporate update.

"We were very pleased to announce this quarter on FDA approval of an expanded access program that will provide critical limb ischemia patients who are not suitable for enrollment in our Phase III trial with access to PLX-PAD while the trial is ongoing," said Yaky Yanay, Co-Chief Executive Officer and President of Pluristem. "Importantly, the FDA approved reimbursement for the procedure with a cost recovery that may provide a key reference point for eventual commercial pricing, assuming product approval."

"During the fiscal first quarter and subsequent period, we continued to make progress advancing our pipeline of novel placenta-based cell therapy products in multiple indications," Mr. Yanay continued ", we are making good progress in enrolling patients in both ongoing Phase III clinical trials of PLX-PAD in critical limb ischemia (CLI) and the treatment of muscle injury following hip fracture. We were pleased to expand the studies to Israel, following the Israel's Ministry of Health approvals, in addition to existing sites in the U.S. and Europe, which we expect should allow us to reach our enrollment goals faster. We look forward to data from these advanced trials, which are being funded by more than \$16 million in grants from the European Union's Horizon 2020 program, as we continue on the path toward becoming a commercial-stage regenerative medicine company."

"Regarding our second cell therapy product, PLX-R18, which we are developing for several hematopoietic indications, during the quarter we received Orphan Drug Designation for the treatment of graft failure and incomplete recovery following hematopoietic cell transplantation. We are currently evaluating this novel therapeutic cell therapy product in an open-label Phase I clinical trial being conducted in the U.S. and Israel, and we look forward to data that will help guide our next steps in the development of this promising therapeutic," Mr. Yanay concluded.

## Financial Update:

As of September 30, 2018, Pluristem had approximately \$30 million in resources, out of which \$22.5 million in cash and cash equivalents, bank deposits and restricted deposits, and remaining are derived from approved grants to be payable over time. The Company's net cash used for operating activities was \$8.5 million for this quarter.

#### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel 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 belief that, with respect to its two Phase III clinical trials of PLX-PAD in CLI, the opening of trial sites in Israel, in addition to existing sites in the U.S. and Europe, should allow it to reach it enrollment goals faster, and also opens the door to potential commercial approval in Israel, its belief that it may be reimbursed for the procedure relating to its expanded access program for CLI with a cost recovery that may provide a key reference point for eventual commercial pricing, assuming product approval, and its belief that the data derived from its open-label Phase I clinical trial being conducted in the U.S. and Israel relating to PLX-R18 will help guide its next steps in the development of the promising therapeutic cell therapy product. 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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