Pluristem Announces DMC Recommendation Following Interim Analysis of its Phase III CLI Study

- **The CLI study is unlikely to meet its primary endpoint by the time of the final analysis**
- **Substantial low number of events in the placebo group in the CLI study decreased the statistical power of the study to meet its primary endpoint**
- **PLX-PAD was well tolerated, and no safety concerns were raised**
- **Company to terminate the CLI study to focus on different therapeutic areas in its pipeline and expects three clinical readouts within the coming calendar year**
- **Company will host conference call on December 9, 2020, at 8:30 AM ET / 3:30 PM Israel time**

HAIFA, Israel, December 9, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological therapeutic products, today announced that the independent Data Monitoring Committee (DMC) of its global pivotal Phase III study for the treatment of critical limb ischemia (CLI) issued its recommendation letter following the interim analysis. The clinical dataset was reviewed by the independent DMC for safety and analysis of the primary endpoint of amputation-free survival, defined as time to occurrence of major amputation of the index leg or death.

Based on the review, the DMC concluded that the CLI study is unlikely to meet the primary endpoint by the time of the final analysis. The DMC advised the Company that the CLI study population has experienced a substantial low number of events (major amputation of the index leg or death), different from what is known in clinical medicine for the rate of these events in this patient population. The lower than anticipated event rate in the placebo group reduced the statistical power of the study to meet its primary endpoint.

DMC noted that PLX-PAD was well tolerated, and no significant safety concerns were raised during the study.

Following the DMC's recommendation, the Company decided to terminate the CLI study. Currently, the Company continues to be blinded to the CLI study clinical data.

"We are deeply disappointed by the outcome of the CLI interim analysis. In light of the DMC's recommendation, we decided that it would be in the best interests of the Company and its shareholders to terminate the CLI study and focus our resources and efforts on our other lead indications," stated Pluristem CEO and President, Yaky Yanay.

"We expect to present topline clinical results during calendar year 2021, including our Phase III study in muscle regeneration following hip fracture, Phase II studies in Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19 and our Phase I study in incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT). Pluristem is well positioned to advance and support future development of these indications."

"Throughout the years, we have developed unique and propriety expertise, knowhow and intellectual property, alongside a diverse clinical pipeline and we possess a state-of-the-art cell manufacturing facility. We believe our platform and technology will be a meaningful force in regenerative medicine in a variety of therapeutic areas," Mr. Yanay concluded.

The Company will host a conference call on December 9, 2020 at 8.30AM ET / 3.30PM Israel time. It can be accessed via:

https://webcasting.brrmedia.co.uk/broadcast/5fc769bd2ac82b2af52e277b

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to 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; a Company-owned and operated GMP-certified manufacturing and research facility; 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 that it expects topline clinical results during the calendar year 2021 with respect to its Phase III study in muscle regeneration following hip fracture, its Phase II studies in ARDS associated with COVID-19 and its Phase I study in incomplete hematopoietic recovery following HCT, its belief that it is well positioned to support the future development of these indications and its belief that its platform and technology will be a meaningful force in regenerative medicine in a variety of therapeutic areas. 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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