Pluristem Therapeutics CEO Issues Shareholder Update

HAIFA, Israel, February 10, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel cell therapy products, today issued an update to its shareholders from its Chief Executive Officer and President, Yaky Yanay.

Dear Fellow Shareholders,

Today we announce Pluristem's update for the second quarter of fiscal 2020, including recent achievements and our next short-term milestones. Recently, Pluristem's management attended the annual J.P. Morgan Healthcare Conference in San Francisco, and this year it was clear more than ever that the pharmaceutical industry is significantly increasing its interest in cell and gene therapy. Many of the discussions and conversations about cell and gene therapy focus on the technological gaps and the lack of manufacturing platforms. As you know, Pluristem considers its manufacturing capabilities to be one of its key competitive advantages. There is significant interest in our platform technology and in the fact that we have strong industrial manufacturing capabilities and high batch to batch consistency, while maintaining strong pipeline aimed for valuable markets with unmet medical needs. The discussions during this week confirmed that we hold a leading position in the field of advanced therapies. My goal is to materialize this advantage to also benefit our shareholders.

During this past quarter, we were very focused on completing our pivotal Phase III clinical studies. We made significant advancements in both of our Phase III studies for PLX-PAD, including achieving the 75% enrollment milestone in our multinational Phase III Critical Limb Ischemia (CLI) study and the 50% enrollment milestone in our multinational Phase III study in muscle regeneration following hip fracture. I am very pleased with the fact that we have kept enrollment rates high. We have strong cooperation from our clinical sites, and we are pushing forward to complete our mission to be the first company in U.S. and Europe with approved treatments for unmet medical needs such as CLI and muscle regeneration.

As recently announced, we have also concluded a thorough market analysis of the U.S. CLI market. This market access study, which included interviews with dozens of U.S. payers and key opinion leaders, demonstrated what we believe is a significant need with a potential addressable market estimated between $2 and $6 billion for PLX-PAD in the United States. During this past quarter we also made important progress with our preparation for commercialization of CLI and advanced our relationships and discussions with potential collaborators and other stakeholders.

We have established a wholly owned subsidiary, based in Berlin, Germany, understanding the importance of a physical presence in our strategic markets, and advancing research and development activities with our long-term partner, the Charité and BCRT (BIH Center for Regenerative Therapies) of Berlin.

As we previously reported, Pluristem submitted a proposal to the U.S. Biomedical Advanced Research and Development Authority (BARDA) for a project designed to demonstrate the superiority of our PLX-R18 therapy versus current standards of care in the treatment of Acute Radiation Syndrome (ARS). We were recently notified by BARDA that the proposal is still being evaluated and a final answer should be provided soon. We recognize BARDA's near-term focus may have shifted to the coronavirus threat over the past few weeks and believe that a decision made regarding PLX-R18 will be made within the context of the agency's broader current and future needs. Once we receive a response to our proposal from BARDA, we will announce it.

Financial Update:
As of December 31, 2020, Pluristem had approximately $17.5 million in cash and cash equivalents, bank deposits and restricted deposits. We strengthened our cash position in January by an additional approximately $4 million that was raised through our Open Market Sales Agreement with Jefferies LLC from several family offices and institutional investors that have shown long term interest in Pluristem.

The coming quarters are extremely important to us all, as Pluristem is well positioned to successfully meet milestones and become a global leading regenerative medicine company.

Sincerely,
Yaky Yanay
Chief Executive Officer and President

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 its next milestones, the pharmaceutical industry's increasing interest in cell and gene therapy, materializing advantages for the benefit of shareholders, its belief regarding significant need and potential addressable market for PLX-PAD in the United States, preparation for commercialization of CLI, its proposal to BARDA, the timing of BARDA's response and further shareholder communications. 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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