Pluristem Therapeutics Recaps Key Opinion Leader Meeting on Peripheral Artery Disease (PAD)

Presentations underscore significant need for new PAD treatment approaches and the potential of cell therapy to improve patient outcomes while reducing healthcare costs

HAIFA, Israel, December 17, 2018 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today provided a recap of the Key Opinion Leader (KOL) breakfast meeting on peripheral artery disease (PAD) that the Company hosted on Friday, December 14 in New York. The meeting focused on the current treatment landscape, unmet medical need, economic impact and potential market opportunities for treating patients with PAD, a serious but common circulatory problem characterize by a blockage of the arteries and reduced blood flow to the limbs. Risk factors include smoking, diabetes, heavy weight, cardiovascular problems & hypertension.

In addition to a management update on the Company's ongoing late-stage development of PLX-PAD, the meeting featured comprehensive presentations by John Lantis, MD, Vice Chairman of the Department of Surgery and Chief of Vascular and Endovascular Surgery at Mount Sinai West, and Mary L. Yost, MBA, Co-Founder of The Sage Group.

"The presentations offered by these Key Opinion Leaders underscore the significant unmet medical need in PAD, and particularly critical limb ischemia (CLI), and highlight the potential of cell therapies in improving patient outcomes while addressing the significant economic burden of treating this serious cardiovascular disease," said Yaky Yanay, Co-CEO and President of Pluristem. "We believe PLX-PAD has the potential to become the standard of care in CLI treatment, and we look forward to data from our ongoing multinational pivotal Phase III CLI study."

Among the highlights:

- **PAD represents a significant unmet medical need.** Major amputation and death are the ultimate consequences of critical limb ischemia (the most severe form of PAD); a one-year amputation and mortality rates range from 30-40%

- **PAD carries a five-year mortality rate higher than most cancers.** The 5-year mortality rate from PAD (64%) is higher than most of cancers.
- **Many CLI patients do not benefit from, or are not candidates for, current revascularization techniques.** 85% of CLI patients undergo surgical or endovascular procedures to restore blood flow, however, 20% of these do not benefit. The remaining 15% are not candidates for revascularization
- **Cell therapy offers a potential cure.** Allogenic placental cell therapies such as PLX-PAD appear to be more potent and efficient then autologous cell and gene therapies.

"Potentially, cellular therapies that can actually modify the diseased tissue into healthier more responsive tissue offer the possibility of cure and not just a treatment," commented Dr. Lantis. Early studies have shown significant clinical benefit from this type of therapy and I am very pleased that significant further clinical research is well underway".

- **PAD is more prevalent than most chronic diseases.** It is estimated that 19.8 million people suffer from PAD in the U.S. alone. This is expected to increase to 24.5 million by 2030
- **PAD is underestimated, underdiagnosed and undertreated.** This results in higher morbidity, mortality and costs than currently estimated
- **The total annual economic burden of PAD is $223-$414 billion.** By comparison, the annual economic burden of diabetes is estimated to be $176 billion
- **Estimated U.S. market opportunity for cell therapy is $4.4-&9.1 billion.** A $35,000 treatment cost for cell therapy is based on current PAD/CLI treatment costs.

"The global economic burden of CLI is staggering, and exceeds the burden of diabetes, cancer and carotid artery disease combined," commented Ms. Yost. "Furthermore, with an aging global population and continued growth in the prevalence of diabetes, this burden is only projected to increase, which speaks to the urgent need for new innovative and cost-effective treatments for this serious disease."

Pluristem's pivotal Phase III study of PLX-PAD cells in the treatment of CLI, which has received an $8 million grant from the European Union's Horizon 2020 program, has received the U.S. Food and Drug Administration's (FDA) Fast Track designation for the treatment of CLI and has been included in the European Medicines Agency (EMA) Adaptive Pathways program, which may lead to early conditional marketing authorization based on an interim analysis following follow up on half of the total 246 patients to be enrolled in the study. The FDA recently cleared PLX-PAD for its Expanded Access Program (EAP), with cost recovery, for the treatment of patients with CLI who are not eligible for Pluristem's Phase III study.

For PAD KOL day slides- link
For PAD KOL day webcast- link

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. 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; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; 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; our patents may not be sufficient; our products may harm recipients; changes in legislation; 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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