

## Pluristem Therapeutics Reports Successful Case Study in Treatment of Buerger's Disease Patient

- Buerger's disease is a severe vascular inflammatory disease associated with high risk of amputation
- Patient was at a pre-amputation stage and was treated with PLX-PAD cell therapy under compassionate use treatment
- After a 12 month follow up period, PLX-PAD restored peripheral blood supply to the injured limb and prevented amputation
- PLX-PAD was granted Orphan Drug Designation by the FDA for the treatment of Buerger's disease and an expanded access program for the treatment of critical limb ischemia

**HAIFA, Israel, January 9, 2019** - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative-medicine company developing novel placenta-based cell therapy products, today reported a successful one-year follow up of a compassionate use treatment in a Buerger's disease patient treated with Pluristem's PLX-PAD.

The thirty-six years old patient, who was diagnosed with Buerger's disease approximately four years ago, displayed painful, non-healing ulcers on his foot. Available medical interventions, including revascularization procedures, were unsuccessful in restoring sufficient blood flow to the affected limb and the patient progressed to a pre-amputation stage. Following his physician's request and regulatory approval, patient was given a compassionate use treatment of PLX-PAD cells, consisting of two administration to the foot and calf, approximately eight weeks apart.

"The patient was in an advanced stage of Buerger's disease and was facing amputation," said Prof Boris Yoffe, Department of General and Vascular Surgery at the Barzilai Medical Center in Israel. "Following treatment with PLX-PAD cells, we observed demonstrable restoration of the patient's peripheral blood supply to the injured limb, which was manifested by a significant improvement in color, warmth, wound size and reduced pain. One year following treatment, the wound is now fully closed, the patient was able to resume normal activities and amputation was prevented. This treatment highlights PLX-PAD's ability to reduce inflammation, stimulate growth of new blood vessels and support treatment in ischemic conditions such as Buerger's disease and Peripheral Arterial Diseases (PAD). Additionally, the other limb, which was in earlier stages of the disease, also showed signs of improvement demonstrating the cells' ability to prevent progression of the disease and act as a potential systemic treatment. I am highly encouraged by

these results providing hope for Buerger's disease patients and am happy to see the significant improvement in the patient's medical condition, quality of life and overall wellbeing."

"The positive outcome experienced by the patient reflects what we believe is the broad potential of PLX-PAD in treating a wide range of vascular and inflammatory conditions, where improved treatment paradigms are surely needed," said Zami Aberman, Chairman & Co-CEO of Pluristem. "While we advance PLX-PAD in our ongoing multinational Phase III clinical study in critical limb ischemia (CLI), we are pleased to see more supportive evidence of patients benefiting from our PLX regenerative agents. We are now enabling access to PLX-PAD treatment through our U.S. Expanded Access Program in CLI and will explore to expand the program to include Buerger's disease patients."

Buerger's disease (thromboangiitis obliterans) is a recurring progressive inflammatory disease resulting in clotting of small and medium size arteries and veins of the hands and feet. The specific cause of Buerger's disease remains unknown. The risk for developing Buerger's disease increases with heavy smoking. There is no cure available today for Buerger's disease. The initial symptoms of Buerger's disease often begin with claudication, progressing to pain at rest. If the condition is severe, complications like gangrene may accrue which may lead to limb amputation.

PLX-PAD has been granted Orphan Drug Designation by the FDA for the treatment of Buerger's disease.

## **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 states its belief that the PLX-PAD treatment for a patient's Buerger's disease highlights PLX-PAD's ability to reduce inflammation, stimulate growth of new blood vessels and support treatment in ischemic conditions such as Buerger's disease and PAD, its belief that PLX-PAD cells have the ability to prevent the

progression of Buerger's disease and act as a potential systemic treatment, its belief regarding the broad potential of PLX-PAD in treating a wide range of vascular conditions and its exploring the possibility of broadening its ongoing CLI Expanded Access Program to include Buerger's disease patients. 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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