



## **FDA Clears Pluristem's Expanded Access Program to Initiate Treatments of Critical Limb Ischemia Outside of Ongoing Phase III Study**

- *Program Allows for Collection of Real-World Data Alongside the Company's Ongoing Phase III Study in CLI*
- *FDA May Also Allow Pluristem to Be Compensated for the Cost of Treatment*

**HAIFA, ISRAEL, January 9, 2018** -- [Pluristem Therapeutics Inc.](#) (NASDAQ: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that the U.S. Food & Drug Administration (FDA) has cleared the Company's Expanded Access Program (EAP) for the use of its PLX-PAD cell treatment in patients with Critical Limb Ischemia (CLI). EAP allows the use of an investigational medical product outside of clinical trials and is usually granted in cases where patients are unsuitable for inclusion under the study protocol and the patient's condition is life-threatening with an unmet medical need.

As part of the program, Pluristem's PLX-PAD cell therapy will be made available to a limited number of Rutherford Category 5 CLI patients in the U.S. who are unsuitable for revascularization and cannot take part in the Company's ongoing Phase III clinical study, which is currently enrolling patients in the U.S. and Europe. The Company's PLX-PAD program has already been selected for accelerated approval pathways in both regions, including the FDA's Fast Track Designation and the European Medicines Agency's (EMA) Adaptive Pathways program.

"This is a true vote of confidence by the FDA in our cell therapy and a landmark achievement for Pluristem and its shareholders. It gives us the ability to begin treatments using our cell product, offering treatment to certain CLI patients who have poor therapeutic options, while also collecting real-world data alongside our ongoing Phase III clinical study," said Yaky Yanay, Co-CEO and President of Pluristem. "We are hopeful that the FDA may also allow us to be compensated for the costs of treatment, which can support our work developing effective cell therapies for millions of patients worldwide."

CLI is an advanced stage of peripheral artery disease where fatty deposits block arteries in the legs, leading to pain, non-healing ulcers, and gangrene. Patients with CLI have a high risk of amputation and death, and those unsuitable for revascularization are left with no adequate treatment options. Pluristem's PLX-PAD cell therapy utilizes placental cells to secrete a range of therapeutic proteins that trigger the body's own repair mechanisms, allowing it to grow blood vessels, bring oxygenated blood to damaged tissue, and heal itself faster.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells, and is entering late-stage trials in several indications. Our 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 that its PLX-PAD cell therapy will be made available to a limited number of Rutherford Category 5 CLI patients in the U.S. and that the FDA may allow it to be compensated for the costs of treatment, which can support the Pluristem's work to develop effective cell therapies for millions of patients worldwide. 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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