U.S. FDA Approves Cost Recovery for PLX-PAD under Expanded Access Program in the Treatment of Critical Limb Ischemia

- ***Pluristem enters into agreement with WideTrial Inc. to conduct the program***
- ***WideTrial will purchase PLX-PAD cell products from Pluristem***
- ***Program makes investigational treatment available to CLI patients who are unsuitable for inclusion in the Company's ongoing multinational Phase 3 clinical study***
- ***Allows for collection of real-world data concurrent with the Phase 3 study***

HAIFA, Israel and San Francisco, CA, October 16, 2018 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, and WideTrial Inc., a privately-held third-party sponsor of authorized Expanded Access Programs (EAPs), today announced that the parties have entered into agreement to initiate an FDA-cleared EAP for Pluristem's cell therapy product, PLX-PAD, for the treatment of critical limb ischemia (CLI). The parties further announced that the FDA has authorized WideTrial to charge payment for the PLX-PAD EAP treatment. Under the terms of the EAP, an initial 100 Rutherford-5 CLI patients who are ineligible for inclusion under Pluristem's ongoing Phase 3 study protocol, and whose condition is life-threatening, will be enrolled.

"Patients suffering from critical limb ischemia are often unsuitable for revascularization and therefore experience poor clinical outcomes, including amputation. The condition can be fatal if left untreated," said Yaky Yanay, Co-CEO and President of Pluristem. "We believe the FDA's decision to approve this Expanded Access Program with cost-recovery for this novel and potentially life-saving cell therapy reflects the Agency's comfort with the safety profile of PLX-PAD, and recognition of its potential use in treating CLI patients who have few remaining treatment options. As we progress through the EAP, we look forward to generating valuable real world data concurrent with our ongoing 246-patient Phase 3 study that we are currently enrolling in U.S., Europe and Israel. Together, these clinical initiatives are expected to yield a significant body of evidence that we believe will support the safety and efficacy of PLX-PAD and may represent a significant advancement in the treatment of CLI."

"We are pleased to make PLX-PAD more widely available to CLI patients in need while allowing Pluristem's management to stay focused on its ongoing Phase 3 clinical study," said Jess Rabourn, Chief Executive Officer of WideTrial. "Expanded Access Programs allow pre-market treatment use of new medicines by patients who suffer from severe conditions and who cannot enroll in regular clinical studies. These programs can also generate real world data from a wider range of patients in the target population, insights from which could help inform further development of this particular study drug."

Pluristem's PLX-PAD program has been selected for accelerated approval pathways in both the U.S. and Europe, including the FDA's Fast Track Designation and the European Medicines Agency's (EMA) Adaptive Pathways program.

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, particularly later stages of the disease (Rutherford Categories 5 and 6) 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 WideTrial

WideTrial is a third-party sponsor of small-group and large-group Expanded Access programs for patients who do not meet the enrollment criteria of traditional research studies. The company uses its scalable platform to make pre-market access more attractive to drug developers and to improve the inclusiveness of the overall drug development process.

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 study data in multiple indications for its patented PLX cells and is entering late stage studies 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 discusses the timing, description and parameters of its EAP with Widetrial, its belief that the FDA's approval of the EAP reflects its comfort with the safety profile of PLX-PAD and may lead to recognition of its potential use in treating CLI patients who have few remaining treatment options and that the results of the EAP are expected to yield a significant body of evidence that it believes will support the safety and efficacy of PLX-PAD and may represent a significant advancement in the treatment of CLI. 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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