



In Its Path Towards Marketing, Pluristem Provides Highly Favorable Market Access Data Regarding the Critical Limb Ischemia Market in U.S.

HAIFA, Israel, February 3, 2020 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological products, today announced results from a market access comprehensive research study conducted by Marwood Group, a healthcare advisory firm, for the critical limb ischemia (CLI) market in the U.S. The report included data from published literature as well as direct interviews regarding Pluristem's PLX-PAD regenerative cell therapy with dozens of physicians, who are key opinion leaders (KOL) in CLI, and with payers covering millions of lives. Pluristem believes that the in-depth report reflects a favorable market for PLX-PAD, which is currently in a global Phase III study with clinical sites in the U.S., Europe, and Israel. According to the report, CLI is a significant unmet need indication, and constitutes a significant burden on the U.S. healthcare system. The report suggests that the addressable market for PLX-PAD for Rutherford 5 CLI patients that are unsuitable for revascularization is expected to reach \$2 billion by 2023. In addition, the physicians interviewed as part of the study suggest that they would use the PLX product in cases where multiple medical interventions are needed per year. Based on the report, and assuming such an approach, this could support an annual addressable market in the U.S. of \$6 billion.

The incidence of CLI in the U.S. is rising, driven by an aging population and the increase in the prevalence of diabetes, both underlying drivers for CLI. Currently, there are between 2 and 3 million CLI patients in the U.S., with 500,000 to 600,000 new cases per year. Of these, 30% to 35% are classified as Rutherford 5, the target population in Pluristem's ongoing Phase III study. Approximately half of Rutherford 5 and Rutherford 6 CLI patients have diabetes, and this patient population has a 50% higher probability of amputation than patients without diabetes due to the rapid progression of the disease.

About 35% of CLI patients today are unsuitable for revascularization surgery, according to KOLs and market researches in this field, and face high rates of death and amputation, which carries high medical and personal costs. The average cost for major amputation in the U.S. is estimated at \$47,000, with ongoing annual costs for amputees estimated at \$75,000 and estimated lifetime cost of \$500,000-\$800,000. The current cost of potential amputation, and of treating CLI, is well recognized by payers and many of them see amputation as a cost benchmark for a new treatment like PLX-PAD.

As disclosed in the report, vascular surgeons who typically treat CLI expressed interest in using PLX-PAD, which is provided as an outpatient setting, thus potentially reducing the need for hospitalization. Both KOLs and payers confirmed that amputation free survival (AFS), Pluristem's primary efficacy endpoint for its Phase III study, is an endpoint that should drive adoption. Pluristem's Phase III study population includes Rutherford 5 patients who are considered unsuitable for revascularization surgery. In addition to treating these patients, more than three-quarters of vascular surgeons expressed an unmet need and willingness to use PLX-PAD for patients with non-healing wounds and who already receive two revascularizations, or more, annually.

"Based on this thorough market report, it is clear to us that CLI patients, and especially those unsuitable for revascularization that are suffering from a very poor quality of life and carry a heavy burden on the health care system, require better medical solutions. We believe that this market report highlights payers' and physicians' interest in PLX-PAD as an alternative method of care for CLI patients," said Yaky Yanay, Pluristem President and CEO. "We also believe that this market report validates our understandings regarding the potential substantial market for our PLX-PAD product in the U.S., and the importance of implementing novel regenerative medicine in CLI to control increased healthcare spending. Pluristem is committed to finding a solution for CLI and believes that our Phase III study will show promise in preventing amputation and help improve the lives of millions of CLI patients."

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.

About Marwood Group

Marwood Group is a healthcare focused strategic advisory and financial services firm headquartered in New York City with offices in Washington, D.C. and London. Marwood Group's consulting practice, Marwood Group Advisory, is a leading healthcare-focused strategic advisory firm that provides due diligence, market access, and life cycle management consulting services for life sciences companies and investors. Marwood operates at the intersection of healthcare policy analysis, market diligence and strategic consulting; Marwood's senior team includes

former healthcare and life sciences operators, investment bankers, and veterans of top-tier strategy consulting firms as well as former senior-level government officials and policy makers. To inquire about Marwood's work in the life sciences sector, please contact Nayan Ghosh at nghosh@marwoodgroup.com.

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 potential size of the U.S. market for patients suffering from CLI, the potential benefits and use of PLX-PAD in the treatment of CLI over the current standard of care in the context of preventing amputations and in place of revascularization, the belief that the market report highlights payers' and doctors' interest in PLX-PAD as an alternative method of care for CLI patients, the belief that the market report validates its understanding regarding the potential market for its PLX-PAD product in the U.S. and the importance of implementing novel regenerative medicine in CLI to control increased healthcare spending, and the belief that its Phase III study will show promise in preventing amputation and help improve the lives of millions of CLI 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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