



Pluristem Granted Manufacturer Authorization and Good Manufacturing Practice (GMP) Certification by Israel's Ministry of Health, Supporting Pivotal-Stage Studies

- Authorization is also under the provision of the Conformity Assessment and Acceptance of Industrial Products (CAA) agreement between Israel and the European Union (EU), which will serve to qualify Pluristem's facilities for future marketing in the EU as well.

HAIFA, ISRAEL, December 12, 2017 -- [Pluristem Therapeutics Inc.](#) (Nasdaq: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today it received a GMP certification and manufacturer/importer authorization from Israel's Ministry of Health (MOH). The GMP certificate was granted upon successful audit of Pluristem's facilities.

The MOH approval is required for Pluristem to continue manufacturing its cell therapies for use in ongoing pivotal studies and will also facilitate readiness of manufacturing for marketing of Pluristem's placental cell therapies worldwide. This MOH authorization fulfills the requirements set by the World Health Organization (WHO) and also falls under the provision of the CAA agreement between Israel and the EU, which will also serve to qualify Pluristem's facilities for marketing in the EU as well.

The approval supports the readiness of Pluristem's manufacturing capabilities as the company advances in its pivotal-stage studies. Pluristem is currently enrolling patients in a global Phase III trial of PLX-PAD cells for the treatment of critical limb ischemia and expects to commence a phase III study of PLX-PAD for the treatment of hip fracture following surgery.

The company maintains close relationships with key regulators worldwide relating to the quality expectations for marketing and has already secured Chemistry, Manufacturing, and Controls (CMC) approval from key regulators including the U.S. Food and Drug Administration (FDA), Japan's Pharmaceutical and Medical Devices Agency (PMDA,) and the European Medicines Agency (EMA).

"We are delighted to receive this GMP certification from the Israeli Ministry of Health," said Zami Aberman, Chairman and Co-CEO of Pluristem. "We believe that this authorization affirms our ability to abide by the strict requirements demanded from advanced pharmaceutical companies while being the gold standard in cell therapy manufacturing and development."

About Pluristem Therapeutics

Pluristem Therapeutics is a leading developer of placenta-derived cell therapy products with patented PLX (PLacental eXpanded) cells entering late-stage trials in several indications. Our PLX cell products each release a different 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 3D expansion technology and can be administered to patients

without tissue matching or immunosuppression. Pluristem has company-owned and operated, GMP-certified manufacturing and research facilities, a strong intellectual property position, and strategic relationships with major research and U.S. government institutions.

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 the GMP certification supports the manufacturing of Pluristem's pivotal stage studies and readiness for future marketing as well as complying with future EU marketing purposes, Pluristem's expectation to commence a phase III study in PLX-PAD for the treatment of hip fracture following surgery and its belief that the GMP certification affirms its ability to abide by the strict requirements demanded from advanced pharmaceutical companies while being the gold standard in cell therapy manufacturing and development. 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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