



## **Pluristem Enters Collaboration with Pharmaceutical Company Innovare R&D to Expand Pluristem's ARDS Associated with COVID-19 Program to Mexico**

**HAIFA, Israel, December 29, 2020** - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today it has entered into a collaboration agreement with Mexican pharmaceutical company Innovare R&D to expand its ongoing clinical program of PLX cells in the treatment of Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19 in Mexico. The Phase II study in Mexico is subject to the approval of local authorities, with the goal of being conducted under the U.S. Food and Drug Administration (FDA) cleared [protocol](#).

In accordance with the agreement, Innovare will open clinical sites and enroll patients for the proposed clinical study in Mexico. Innovare will fund the study in Mexico and will purchase PLX cells for the study from Pluristem. Subject to potential positive clinical study results and Mexican regulatory approval for commercialization, the agreement grants Innovare exclusive distribution rights in Mexico to supply PLX cells for treating severe COVID-19 cases complicated by ARDS. All intellectual property and manufacturing rights remain with Pluristem.

With 1,389,430 cases and 122,855 deaths as of [December 29](#), 2020, Mexico's COVID-19 infection and mortality rates have been increasing. Mexico has the highest deaths proportionally to COVID-19 cases or population in the world as of [December 28](#), 2020, as reported by Johns Hopkins University of Medicine.

"We are pleased to join forces with Innovare, a leading innovative company aiming to be part of the solution for combating the COVID-19 pandemic in Mexico," stated Pluristem CEO and President, Yaky Yanay. "Thanks to our key competitive advantage of having in-house manufacturing facility, advanced logistical capabilities, and a global reach, we are able to supply PLX cells to clinical centers around the world while extending our global support for COVID-19 into Latin America. By conducting the study in both the U.S. and Mexico, in parallel to the E.U. and Israel, we are continuing our focus on achieving clinical milestones and objectives, while bringing the potential treatment of PLX cells to those in need."

Gerardo Cárdenas Vogel, CEO of Innovare R&D commented, "As a company that is seeking worldwide partners showing clinical promise for unmet medical needs, we are excited to collaborate with Pluristem. We look forward to leveraging our clinical and commercial

capabilities with Pluristem's advanced cell therapy solution to help develop and potentially bring a much needed treatment for ARDS patients associated with COVID-19 to Mexico."

Pluristem is currently conducting two Phase II studies in ARDS associated with COVID-19 in the U.S., Europe and Israel, an Expanded Access Program in the U.S. and a per patient compassionate use program in Israel.

#### **About Innovare R&D**

Innovare R&D comprises a group of pharmaceutical companies that develop and commercialize drugs in the areas of hematology, immunology, infectious disease, central nervous system, and urology. They established a unique partnering model to collaborate with biopharmaceutical companies in a strategy to proof the applicability of their platform in improving patient's outcomes. Innovare R&D has regional (Mexico) coverage for commercializing products that have already been approved by the FDA/ European Medicines Agency (EMA)/ Health Canada/ Swissmedic/ TGA, while Innovare R&D is leading their own product developments with partners in the U.S. and Europe.

#### **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.

#### **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 Phase II study in Mexico, subject to the approval of local authorities, that it continues to focus on achieving clinical milestones and objectives, while bringing the potential treatment of PLX cells to those in need and potentially bringing a much needed treatment for ARDS patients associated with COVID-19 to Mexico. 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.

**Contact:**

Dana Rubin  
Director of Investor Relations  
972-74-7107194  
[danar@pluristem.com](mailto:danar@pluristem.com)