# United States Congress Passes Bill that Represents a Major Opportunity for Regenerative Therapies

- ***21st Century Cures Act is expected by industry analysts to speed up drug development by accelerating the regulatory approval process***
- ***Pluristem's program for CLI was already selected to rapid pathways in both Europe and Japan, where legislation similar to the 21st Century Cures Act has already been passed***

**HAIFA, ISRAEL, December 13, 2016 --** Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, welcomes and applauds the U.S. Congress' passage of the 21st Century Cures Act. Pluristem believes its PLX-PAD and PLX-R18 cell therapies will meet the criteria outlined by the Act as advanced regenerative therapies that can treat a wide range of disease. The 21st Century Cures Act is expected by industry analysts to speed up drug development by accelerating the regulatory approval process, among other means.

"The 21st Century Cures Act is an extremely significant healthcare legislation that may have a direct and beneficial impact on Pluristem's clinical development programs and progress towards approval for our cell therapies," stated Pluristem CEO Zami Aberman. "Pluristem has a robust portfolio of cell therapies that are designed to treat severe diseases where there is a high unmet medical need. The 21st Century Cures Act should allow for early patient access to cell therapies, while also creating medical and economic benefits for the U.S. healthcare system. The passage of this legislation in the world's largest healthcare market reinforces Pluristem's strategy of pursuing accelerated pathways to market around the globe."

Pluristem's clinical program for CLI is already being developed via both Europe's Adaptive Pathways project and the Japanese PMDA under the new legislation for conditional marketing authorization for regenerative therapies.

**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. The cell products release a range of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

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 forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, we are using forward-looking statements when we discuss our belief that our PLX-PAD and PLX-R18 cell therapies will meet the criteria outlined by the 21st Century Cures Act as advanced regenerative therapies that can treat a wide range of disease, when we discuss the expectation that the Act will speed up drug development by streamlining the regulatory approval process, when we discuss the Act's potential to have a direct and beneficial impact on our clinical development and approval pathways for our cell therapy candidates, and when we discuss our clinical plans regarding the treatment of CLI and improving recovery after surgery for hip fracture, including the plans for FDA protocol submission and possible use of the new U.S. regulatory pathway. 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; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; 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; our patents may not be sufficient; our products may harm recipients; changes in legislation; 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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