



Pluristem's Clinical Advisory Board Prepares Phase II Clinical Trials in Critical Limb Ischemia in Europe and Japan

Company targeting accelerated regulatory pathways to reduce PLX-PAD's time to market

HAIFA, ISRAEL, April 20, 2015 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced that its Clinical Advisory Board for Critical Limb Ischemia (CLI) concluded a key meeting in London, England. During the meeting, Clinical Advisory Board members, including Key Opinion Leaders in the treatment of CLI, outlined the Phase II study design and other critical components of advanced-stage trials for the Company's PLacental eXpanded (PLX) cells in the treatment of this peripheral artery disease.

Pluristem has applied to conduct Phase II trials for CLI in regions with recently established rapid regulatory pathways, including the Accelerated Pathway for Regenerative Therapy in Japan and the Adaptive Pathway in the European Union.

"We believe PLX-PAD could potentially be three years from commercialization, contingent upon successful trials and approval via accelerated regulatory pathways in Japan and Europe. Our Clinical Advisory Board has provided invaluable expertise in generating our Phase II trial protocols, and we are eager to move forward with them," stated Zami Aberman, Pluristem's Chairman and CEO.

Two Phase I studies for CLI, previously completed in the U.S. and Germany, met all primary endpoints. Data from these trials suggested that the cells were safe and potentially efficacious at multiple dosage levels in this indication.

About Critical Limb Ischemia

Patients with Critical Limb Ischemia have leg pain that occurs at rest, or impending limb loss due to sores and wounds that won't heal and can lead to gangrene and amputation. CLI is caused by a severe compromise of blood flow to the affected leg that is usually due to narrowing of the arteries over time as a result of the buildup of fatty deposits called plaque. It is a chronic condition that is associated with a high rate of mortality and the need for frequent hospitalization. Although CLI costs the global health care system billions of dollars each year, current therapies have many limitations. There is growing interest in the development of cellular therapies as alternative treatments.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company's patented PLX (PLacental eXpanded) cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cells are grown using the Company's proprietary three-dimensional expansion technology and are an "off-the-shelf" product that requires no tissue matching prior to administration.

Pluristem has a strong intellectual property position, Company-owned, GMP-certified manufacturing and research facilities, strategic relationships with major research institutions, and a seasoned management team. For more information visit www.pluristem.com, the content of which is not part of this press release.

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, forward-looking statements are used in this press release when we discuss that PLX-PAD could potentially be three years from commercialization via accelerated regulatory pathways in Japan and Europe, or when we discuss that PLX-PAD is safe and potentially efficacious at multiple dosage levels in the CLI indication. 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 surgical 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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