Japan Grants Safety Clearance to Pluristem's PLX-PAD Cells for Use in Clinical Trials

Safety clearance is another step towards the start of Phase II CLI trial via Japan's accelerated approval pathway

HAIFA, ISRAEL, August 12, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI) TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has cleared the Company's PLX-PAD cells for use in clinical trials in Japan. This clearance is required in order to apply for approval to conduct a Phase II study of PLX-PAD in critical limb ischemia (CLI) through Japan's accelerated regulatory pathway for regenerative medicine. This regulatory pathway generally allows for conditional, time-limited marketing approval after a single successful Phase II trial.

"We are very pleased to receive this important safety clearance to administer PLX-PAD to Japanese patients during our anticipated clinical trial in Japan. Our next step is to conclude the discussion of the clinical protocol with the PDMA for our proposed Phase II CLI study. We expect to talk with the PDMA during the last quarter of 2015, and are anticipating that we will receive permission to begin the trial by the end of 2015," stated Pluristem CEO Zami Aberman. "This approval would enable us to potentially start a trial in early 2016."

Safety clearance is the second of three authorizations required by the PMDA prior to commencement of a Phase II trial. Pluristem announced that it received the first of these in May 2015, when the Agency accepted PLX-PAD cells' quality standards and large-scale manufacturing methods. The third and final step, yet to be achieved, is approval of the clinical study design.

About Japan's Conditional time-limited Approval for Regenerative Medicine

Japan's Act on the Safety of Regenerative Medicines went into effect in November 2014. It effectively fast-tracks the approval of cellular therapies and other regenerative medicine treatments for marketing. According to the law, these therapies can receive conditional, time-limited approval for marketing, and be eligible for reimbursement, upon proof of safety and a signal of effectiveness but prior to verification of efficacy. Safety and efficacy need to be confirmed via collection of observational data after the conditional approval. No formal Phase III trial is expected to be required.

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 cells release a cocktail 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, 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 whether the PDMA will allow us to conduct a Phase II clinical study of PLX-PAD in CLI, the expected timing for the approval of our Phase II protocol for CLI by the PDMA, the expected timing for starting a Phase II trial for CLI and whether a Phase III clinical trial will be required. 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; changes in legislation, 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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