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Japan accepts Pluristem's regenerative cells as safe

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Israel's Pluristem Therapeutics Inc. has 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," commented Pluristem's CEO Zami Aberman. "This approval would enable us to potentially start a trial in early 2016," said Aberman.

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.