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Pluristem Therapeutics Inc., Israel's developer of placenta-based cell therapy products, has reached an agreement with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on the design of the final trial needed to apply for conditional approval of PLX-PAD cells in the treatment of critical limb ischemia (CLI).

The approval of the protocol for the 75-patient trial was part of a larger agreement on the development of PLX-PAD via Japan's new accelerated regulatory pathway for regenerative medicine.

"With this achievement we have advanced our strategy to expedite commercialization of our cell products. Pluristem is now positioned favorably to accelerate negotiations with those Japanese pharma companies interested in becoming dominant players in the expanding regenerative medicine market in Japan," stated Pluristem Chairman and CEO Zami Aberman.

The trial will collect data on 75 patients suffering from CLI. These patients will be randomized into three groups of 25. Group one will receive an initial 150 million PLX-PAD cell dose followed eight weeks later by a second 150 million cell dose; group two will be treated with an initial 300 million PLX-PAD cells followed eight weeks later by a second dose of 300 million cells; group three will receive two doses of placebo.

The cells will be injected into a leg muscle using a standard syringe. Efficacy and safety will be determined from outcomes measured nine months after administration of the first dose.

The primary efficacy endpoint will be diagnosis of a patient as CLI-free for 60 days. Pluristem expects to submit the formal Clinical Trial Notification (CTN) to the PDMA, based on the agreement reached with the regulatory body, in early 2016.

The PMDA is expected to respond officially within 30 days. Earlier in 2015, the PMDA cleared PLX-PAD cells for use in clinical studies in Japan, a prerequisite to conducting this clinical trial.

Japan's Act on the Safety of Regenerative Medicines went into effect in November 2014. Its purpose is to facilitate faster

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.