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14 May 2015 | News | By BioSpectrum Bureau

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Singapore: Pluristem Therapeutics, an Israel-based developer of placenta-based cell therapy products, has announced that Japan's Pharmaceuticals and Medical Devices Agency (PMDA) agreed with the proposed quality and large-scale manufacturing methods for PLX-PAD cells for use in clinical trials.

The new regulatory pathway could potentially significantly reduce time to market for cell therapies such as PLX cells.

"Pluristem is emerging as an early leader in the industry's push to enter Japan's newly established accelerated regulatory pathway. It is our hope that the PDMA will approve our application for a Phase I/II clinical study of PLX cells in critical limb ischemia via the Accelerated Pathway," stated Pluristem CEO Mr Zami Aberman.

Japan's Accelerated Pathway for Regenerative Medicine went into effect in November 2014. According to the law, regenerative medicine therapies can receive conditional, time-limited approval for marketing, and be eligible for reimbursement, upon proof of safety and initial proof of efficacy. Safety and effectiveness need to be confirmed within seven years after the conditional approval.