BioSpectrum the business of Bio & Health Sciences

DCGI approves cell therapy for treating critical limb ischemia

21 August 2020 | News

Developed by Stempeutics over a period of twelve years, breakthrough treatment designed to address root cause of the disease at an affordable cost

Mumbai based Cipla has announced that its partner Stempeutics Research Pvt. Ltd has received regulatory approval by the Drug Controller General of India (DCGI) for the launch of Stempeucel® in India.

The product is indicated for the treatment of CLI due to Buerger's Disease and Atherosclerotic Peripheral Arterial Disease. It is the first allogeneic cell therapy product to be approved for commercial use in India and the first stem cell product to be approved globally for CLI treatment.

CLI is a progressive form of peripheral arterial disease that is caused by severe blockage in the arteries thereby reducing blood flow. This may result in the development of sores and wounds in legs and feet with a high risk of limb amputation. It is estimated that about 5 million patients in India are impacted by this debilitating disease.

The product has been developed by Stempeutics over a period of twelve years. The company's proprietary pooling approach provides for an efficient manufacturing process thereby enabling the product to be made accessible to patients at an affordable cost. More than one million doses can be produced from a single set of master cell banks, which is unique in regenerative medicine, thus providing consistent product to patients. The proprietary technology also helps Stempeucel® extend the therapeutic potential of the drug across multiple disease categories.

Under the agreement signed between the two companies, Cipla has received exclusive rights to market and distribute the product in India by leveraging its expansive distribution strengths across the country.