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DCGI gives limited approval to market first allogeneic cell therapy product in India

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Stempeutics Research, a group company of Manipal Education & Medical Group and a Joint Venture with Cipla Group, announced that the Drugs Controller General (India) has granted limited approval for manufacturing & marketing of stem cell based biological product Stempeucel for the treatment of Buerger's Disease.

Buerger's Disease is a rare and severe disease affecting the blood vessels of the legs.

It is characterized by inflammation and occlusion of the vessels of extremities resulting in reduced blood flow to these areas, thus leading to severe pain and ulcers or necrosis, which finally may require amputation.

Stempeucel treatment is designed to enhance the body's limited capability to restore blood flow in ischemic tissue by reducing inflammation and improving neovascularization.

Commenting on the approval of DCGI, Mr B N Manohar, CEO of Stempeutics said, "Obtaining DCGI approval for Stempeucel is an important and historic milestone for Stempeutics. We are the first company in India to achieve such approval. It took almost 9 years to develop Stempeucel for the treatment of Buerger's Disease. European Medicinal Agency has classified Stempeucel as an Advanced Therapeutic Medicinal Product (ATMP) and designated it as an Orphan Drug (ODD) for the treatment of Buerger's Disease. Our goal is to globalize Stempeucel for Buerger's Disease and the market size is approximately $ 1.5 billion worldwide".

Mr Chandru Chawla, Head Cipla New Ventures said, "Today is not only a great day for Stempeutics, but for everyone involved in the responsible development of stem cell therapies. Through Cipla Group's investment in Stempeutics, we have brought the next generation of biologics to address unmet medical needs. Physicians now have an off-the-shelf stem cell therapy in their hand to fight Buerger's Disease. Much like the introduction of antibiotics in the late 1920's, with stem cells we have now officially taken the first step into this new paradigm of medicine."