



Press Release

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

Stempeutics puts India on the “World map of Regenerative Medicine

- ~ DCGI grants limited approval to market Stempeucel® product for treating Critical Limb Ischemia due to Buerger’s disease
- ~ Stempeucel® becomes 5th off-the-shelf Stem cell product to be approved by a Regulatory body, anywhere in the world
- ~ Buerger’s Disease (also known as Thromboangiitis Obliterans) is a major unmet medical need in India and Globally
- ~ Prevalence of Buerger’s Disease is estimated to be 1,000,000 in India and 2 per 10,000 persons in the European Community & USA

India, Bengaluru, May 30th , 2016: Stempeutics Research, a group company of Manipal Education & Medical Group and a Joint Venture with Cipla Group, announced today 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 BN 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 approx. US\$ 1.5Billion 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."

It is a significant milestone for Stempeutics and a satisfying journey for **Manipal Education and Medical Group**, commented **Dr. H. Sudarshan Ballal, Chairman – Manipal Hospitals**

About Buerger's Disease

Buerger's Disease is a recurring progressive inflammation and clotting of small and medium arteries and veins of the feet. It is strongly associated with use of tobacco products primarily from smoking, but also from smokeless tobacco. Stempeucel drug is expected to address the root cause of the disease through anti-inflammatory and immune-modulatory mechanisms. It is expected to induce angiogenesis through release of vascular endothelial growth factors, epithelial growth factors, angiopoietin and improve the perfusion and help the repair and regeneration of the ischemic muscle tissue.

About Stempeutics:

Stempeutics is an advanced clinical stage Biotech Company based out of Bangalore. It was founded by Manipal Education and Medical Group (MEMG) in 2006 and later entered into a strategic alliance with Cipla in 2009. Stempeutics strength lies in developing innovative stem cell products by nurturing cutting edge research and clinical applications through dedicated efforts of its highly qualified team. Its goal is to develop novel stem cell drugs addressing major unmet medical needs with an India first global next approach.

About Manipal Education & Medical Group:

Manipal Education and Medical Group (MEMG) is one of the leaders in the country, in the field of education and healthcare services, with a global footprint. MEMG, through its subsidiaries, provides education and healthcare services in India and internationally. It manages universities and professional institutions, including medical colleges, teaching hospitals, and medical science and technology institutions through which it provides bachelor's and master's degree programs in various streams. It also operates a facility management company, Manipal Integrated Services (MIS) covering student accommodation & hostel management and several other services including food and catering; engineering and maintenance and security and housekeeping. The company also manages healthcare institutions, super-specialty care hospitals, rural maternity and child welfare homes. In addition, the company researches and develops stem cell technologies in various medicine and treatment areas. Manipal Education and Medical Group International India Pvt. Ltd. was founded in 1953 and is based in Bengaluru, India with education colleges and campuses in Antigua, Dubai, Malaysia, and Nepal.

About Cipla Limited:

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. For 80 years, Cipla has emerged as one of the

most respected pharmaceutical names in India as well as across more than 100 countries. Our portfolio includes over 1500 products across wide range of therapeutic categories with one quality standard globally.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognised globally for the pioneering role played in HIV/AIDS treatment as the first pharmaceutical company to provide a triple combination anti-retroviral (ARV) in Africa at less than a dollar a day and thereby treating many millions of patients since 2001.

Cipla's research and development focuses on developing innovative products and drug delivery systems.

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