

Press Release

Stempeutics receives Orphan Drug Designation (ODD) in the European Union for its novel stem cell drug “Stempeucel®” for the treatment of Thromboangiitis Obliterans

- ~ The first allogeneic stem cell drug to be granted ODD status by European Medicinal Agency (EMA) for treating Thromboangiitis Obliterans
- ~ Stempeucel will offer new hope to patients suffering from “Thromboangiitis Obliterans” (also known as Buerger’s Disease) a major unmet medical need in Europe
- ~ Prevalence of “Thromboangiitis Obliterans” is estimated to be 2 per 10,000 persons in the European Community

India, Bengaluru, June 1st, 2015: Stempeutics Research, a group company of Manipal Education & Medical Group and a Joint Venture with Cipla Group, announced today that the European Medicines Agency (EMA) has granted Orphan Drug Designation for its drug Stempeucel® for the treatment of Thromboangiitis Obliterans. Thromboangiitis obliterans or 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 ODD status, **Mr BN Manohar, CEO of Stempeutics said**, "Obtaining Orphan Designation for Stempeucel® in the European Union (EU) is an important regulatory milestone for Stempeutics. The benefits include 10 years of market exclusivity from product launch in the EU, fee reductions, as well as access to the central authorization procedure. This orphan drug designation supports Stempeutics global development strategy for Stempeucel® drug and the goal of providing improved therapies for patients with Thromboangiitis Obliterans”.

“We are pleased to have been granted the benefits of orphan drug designation in Europe," **said Mr Chandru Chawla, Head of Cipla New Ventures**. “We view this as an important milestone to further develop our novel stem cell biological drug Stempeucel in the EU for treating Thromboangiitis Obliterans indication. Additionally, we interpret this as a favourable indication for how the European regulators view our therapy. This significantly increases the commercial potential of our ground breaking therapy.”

About Thromboangiitis Obliterans

Thromboangiitis Obliterans is a recurring progressive inflammation and thrombosis (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 more than 70 years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 150 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 one 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 and has given India and the world many 'firsts' for instance Triomune. In a tightly regulated environment, the company's manufacturing facilities have approvals from all the main regulators including USFDA, UKMHRA, WHO, MCC, ANVISA, and PMDA which means the company provides one universal standard both domestically and internationally.

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