

Press Release

Stempeutics receives Advanced Therapy Medicinal Product (ATMP) classification from European Medicines Agency (EMA) for its novel stem cell drug “Stempeucel®”

- ~ The first stem cell drug based on pooling technology to be granted ATMP classification~
- ~ A new treatment which offers hope to patients suffering from Thromboangiitis Obliterans (Buerger's disease) affecting an estimated 2 out of every 10,000 people in Europe ~
- ~ The first real hope for patients facing limb amputation~

India, Bengaluru & Mumbai, March 23rd, 2015: Stempeutics Research, a group company of Manipal Education and Medical Group and a Joint Venture with Cipla Group, announced today that the European Medicines Agency (EMA) has granted Advanced Therapy Medicinal Product classification for its novel stem cell drug ‘Stempeucel’ which will be used for the treatment of Thromboangiitis Obliterans (TAO). The ATMP classification, approved by the committee for Advanced Therapies (CAT) of the European Medicines Agency, will allow Stempeutics to commercialize the product ‘Stempeucel’ across the European Union region.

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 immunomodulatory 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.

The aim of the ATMP classification is to regulate cell and gene therapy and tissue engineered medicinal products, providing a benchmark for a level of quality compliance for pharmaceutical practices. The regulation provides guidelines to research development companies for following a standardized process in order to obtain approval in EU countries. The regulation also offers incentives to companies involved in developing ATMPs in the European Union, including fee reductions for scientific advice, scientific recommendations on ATMP classification and evaluation and certification of quality and non-clinical data.

Commenting on the ATMP classification, **Mr B N Manohar, CEO of Stempeutics** said, “We are happy to receive ATMP status from the EMA. 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.”

Dr Jeff Karp, Associate Professor of Medicine, Harvard Medical School, who serves as Scientific Advisor to Stempeutics said, “I see Stempeutics as a global regenerative medicine company that could make a significant difference to disease treatment. Stempeutics has an impressive combination of exciting technologies and it has been wonderful to work with the team as they achieve critical milestones and advance their products to patients”.

Mr. Chandru Chawla, Head – Cipla New Ventures, Cipla Limited said: “We are extremely impressed by the incredible journey of innovations embarked by Stempeutics. Stempeucel will be a blessing for European patients who have been suffering with the rare disease – Thromboangiitis Obliterans. Cipla’s front-end presence in Europe will help in creating the right momentum for Access across Europe.”

Commenting on the news, **Dr. Anish Majumdar, CSO of Stempeutics** said “We are pleased to see that the company is being recognized internationally for its R & D and clinical research – the ATMP classification of Stempeucel product by the EMA validates our novel cell therapy technology platform wonderful to work with the team as they achieve critical milestones and advance their products to patients”.

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 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. Cipla’s portfolio includes over 1500 products in various therapeutic categories with one quality standard globally. Cipla’s turnover in 2013/14 was 1.7 billion USD.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla’s emphasis on access for patients was recognized 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 US FDA, UKMHRA, WHO, MCC, ANVISA, and PMDA which means the company provides one universal standard both domestically and internationally.

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