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Stempeutics receives ATMP classification from EMA

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Stempeutics Research, a group company of Manipal Education and Medical Group and a JV with Cipla Group, announced 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 Advanced Therapy Medicinal Product (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.

Commenting on the ATMP classification, Mr B N Manohar, CEO, 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."

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.

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."

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.