

Stempeutics gets Japanese process patent for stem cell drug

Ramnath Subbu

MUMBAI: Stempeutics Research has been granted a process patent from the Japan Patent Office for its novel stem-cell based drug Stempeucel.

Stempeutics is part of the Manipal Education and Medical Group and entered into a strategic alliance with pharma major, Cipla in 2009.

A statement from the company said the novelty covers the method of preparing master cell banks, working cell banks and the final therapeutic product 'Stempeucel' based on the novel pooling technology.

The product will initially be used for treatment of Critical Limb Ischemia (CLI) and is considered a breakthrough treatment option as it addresses the root cause of the disease unlike other drugs which treat the symptoms, the company said.

Stempeucel is derived from specific cells extracted from bone marrow of healthy, adult voluntary donors. The pooling approach allows an efficient manufacturing process with minimum wastage of resources in order to provide the product at an affordable cost to patients.

"The new patent strengthens our position in Japan, which has created an accelerated development path for stem cell therapies," B.N. Manohar, CEO, Stempeutics, said in a statement.

"The regenerative medicine law implemented in Japan allows conditional approval of stem cell products thereby enabling more rapid entry into the Japanese market. We are actively evaluating the potential for accelerated development of Stempeucel product for CLI and Osteoarthritis indications in Japan with strategic collaborations."

Earlier, Stempeucel received Orphan Drug Designation in the European Union to treat Thromboangiitis Obliterans and Advanced Therapy Medicinal Product (ATMP) classification from European Medicines Agency. In March, Stempeutics had received a process patent from the US Patent & Trademarks Office. The company's application to sell the product in the domestic market is awaiting approval from the Drug Controller General of India (DCGI).