

Press Release

Stempeutics receives US process patent for its novel stem cell drug “Stempeucel®”

- ~ The first company in the world to be granted a US process patent for a stem cell drug based on pooling technology
- ~ A new treatment which offers hope for patients suffering from Critical Limb Ischemia (CLI) ~
- ~ Offers new hope to millions of patients whose only treatment option is amputation~

India, Bengaluru, 4th March, 2015: Stempeutics Research, a group company of Manipal Education and Medical Group and a Joint Venture with Cipla Group, announced today that the United States Patent and Trademarks Office (USPTO) granted a US process patent for its novel stem-cell based drug Stempeucel®. Stempeucel® will initially be used for the treatment of CLI and is a breakthrough treatment option which directly addresses the root cause of the disease, unlike other drugs which typically treat the symptoms and not the disease itself.

Critical Limb Ischemia (CLI) is a progressive form of peripheral arterial disease, which blocks the arteries in the lower extremities, resulting into reduction of the blood flow. It is a debilitating disease which affects patients with severe pain in the feet or toes. Insufficient supply of blood flow results into the development of sores and wounds in legs and feet. If left untreated, patients may finally have to undergo amputation of the affected limb as the last treatment option. In the US, the most common current treatments for CLI are characterized by high rates of primary amputations, multiple procedures and high rates of procedure-related complications¹. In such cases, the disease not only affects the quality of life but also increases the economic burden of patients.

Stempeucel® is derived from allogeneic pooled mesenchymal stromal cells extracted from the bone marrow of healthy, adult voluntary donors. The company proprietary pooling approach allows an efficient manufacturing process with minimum wastage of resources in order to provide the product at an affordable cost to patients. This approach also allows more than one million patient doses from a single set of master cell banks, which is unique in regenerative medicine. The proprietary technology allows Stempeucel® to extend the therapeutic potential of the drug across multiple disease categories.

Commenting on the US patent, **Mr B N Manohar, CEO of Stempeutics** said, “The patent granted by USPTO is a strong recognition for Stempeutics for its sustained excellence of scientific and clinical work and underscores the global leadership in allogeneic, pooled MSC technology. We believe that the Stempeucel® product is a game-changer offering an advanced therapeutic treatment for millions of patient suffering with this dreadful disease.”

Mr Chandru Chawla Head Cipla New Ventures said, “Through Cipla Group’s investment in Stempeutics, we are demonstrating a firm commitment bringing the next generation of biologics in order to address unmet medical needs. With this novel Stempeucel technology, we are supporting Stempeutics discovery of this first-of-its-kind regenerative medicine.”

Stempeutics has already submitted its applications to Drug Controller General of India (DCGI) to obtain marketing authorisation approval for Stempeucel®. The availability of the product in the market is subjected to DCGI approvals.

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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Critical limb ischemia: a global epidemic. A critical analysis of current treatment unmasks the clinical and economic costs of CLI. Allie DE1, Hebert CJ, Lirtzman MD, Wyatt CH, Keller VA, Khan MH, Khan MA, Fail PS, Vivekananthan K, Mitran EV, Allie SE, Chaisson G, Stagg SJ, Allie AA, McElderry MW, Walker CM.