



## Press Release

### **US patent office issued notification to grant Patent to Stempeutics for its innovative stem cell drug “Stempeucel” for treating Critical Limb Ischemia (CLI)**

- ✓ **First “Made in India” Biologics receiving such patent from US for treating dreadful disease CLI**
- ✓ Critical Limb ischemia (CLI) is a severe blockage in the arteries which results in reduced blood flow which in turn may result in poor quality of life with a high risk of leg amputation and death.
- ✓ Stempeucel® a cultured, pooled, allogeneic Mesenchymal Stromal Cells derived from the bone marrow of healthy, adult volunteers has been developed for the treatment of Critical Limb Ischemia (CLI).
- ✓ The US patent is for the method of treating ischemia by administering pooled allogeneic mesenchymal stromal cells.
- ✓ The Composition is administered intramuscularly via one or more injections including calf muscle region, thigh region, at or along or in the course of a constricted vessel or any combination and local administration at or around the site of an ulcer, gangrene, or wound.
- ✓ The treatment is characterized by a parameter comprising reduction in rest pain, healing of ulcer, healing of necrosis, healing of gangrene, healing of lesion, healing of wound, increase in ankle pressure, increase in ankle-brachial pressure index (ABPI), increase in transcutaneous partial oxygen pressure (TcPO<sub>2</sub>) and increase in vasculogenesis or any combinations thereof.

**India, Bengaluru, October 30<sup>th</sup>, 2019:** Stempeutics Research, a group company of Manipal Education and Medical Group, announced today that the United States Patent and Trademarks Office (USPTO) issued notice of allowance to grant the US patent for ‘Management of Critical Limb Ischemia (CLI) using Pooled Mesenchymal Stromal Cell product Stempeucel®’. Stempeucel® for the treatment of CLI is a breakthrough treatment option which directly addresses the root cause of the disease, unlike other drugs that 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 in reduced blood flow. It is a debilitating disease which affects patients with severe pain in the feet or toes. Insufficient supply of blood flow results in the development of sores and wounds in legs and feet. If left untreated, patients may finally have to undergo the 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 complications. 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's 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, "This very important patent comes at the right time, just ahead of our planned PreIND meeting with US FDA. The patent being 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 patients suffering from this dreadful disease."

**Prof. Polani Seshagiri, a Stem Cell and Developmental biologist from the Indian Institute of Science-Bangalore, said,** "I am impressed with the scientists working at the cutting-edge stem cell biotechnology at Stempeutics. In an industry that demands constant technological and scientific advances, a robust patent portfolio covering core innovations strengthens Company's competitive edge. Stempeutics through its research innovations is demonstrating a firm commitment in bringing new generation of stem cell-based biologics in order to address unmet medical needs"

Stempeutics is currently conducting a Phase 4 trial for CLI due to Buerger's Disease and a Phase 3 trial for CLI due to Atherosclerotic Peripheral Arterial Disease in India.

### **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 strategic alliances with Cipla in 2009 and with Kemwell in 2019. Stempeutics's 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 India first global next approach.

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