

Press Release

## Cipla and Stempeutics collaborate for launch of Stempeucel®, first ‘Made in India’ Cell Therapy to treat Critical Limb Ischemia (CLI)

- First approved allogeneic cell therapy product globally for the treatment of CLI
- Developed by Stempeutics over a period of twelve years, breakthrough treatment designed to address root cause of the disease at an affordable cost
- Cipla to market and distribute the drug in India to provide patient access

**India, Mumbai, August 17<sup>th</sup>, 2020:** Cipla Limited (BSE: 500087; NSE: CIPLA EQ) referred to as “Cipla” today announced that its partner Stempeutics Research Pvt. Ltd has received regulatory approval by the Drug Controller General of India (DCGI) for the launch of Stempeucel® in India. The product is indicated for the treatment of CLI due to Buerger’s Disease and Atherosclerotic Peripheral Arterial Disease. It is the first allogeneic cell therapy product to be approved for commercial use in India and the first stem cell product to be approved globally for CLI treatment.

The product has been developed by Stempeutics over a period of twelve years. The company's proprietary pooling approach provides for an efficient manufacturing process thereby enabling the product to be made accessible to patients at an affordable cost. More than one million doses can be produced from a single set of master cell banks, which is unique in regenerative medicine, thus providing consistent product to patients. The proprietary technology also helps Stempeucel® extend the therapeutic potential of the drug across multiple disease categories. Under the agreement signed between the two companies, Cipla has received exclusive rights to market and distribute the product in India by leveraging its expansive distribution strengths across the country.

CLI is a progressive form of peripheral arterial disease that is caused by severe blockage in the arteries thereby reducing blood flow. This may result in the development of sores and wounds in legs and feet with a high risk of limb amputation. It is estimated that about 5 million patients in India are impacted by this debilitating disease. With the current contemporary vascular techniques, it is estimated only 25% of patients can be managed with satisfactory clinical outcomes.

Stempeucel® is a breakthrough treatment which is designed to enhance the body's limited capability to restore blood flow in ischemic tissue. It is derived from allogeneic pooled mesenchymal stromal cells isolated from the bone marrow of healthy, adult voluntary donors. It directly addresses the root cause of the disease by reducing inflammation, stimulating growth of collateral blood vessels and repairing damaged muscle, thereby reducing the pain, healing the ulcers and salvaging the affected limb. The drug is administered through intramuscular injections around the calf muscle region and around the site of ulcers.

Currently, Stempeutics is working on a strategy for other international markets including US, EU and Japan. The global critical limb ischemia treatment market expected to generate USD 5,390 million by 2025, at a CAGR of 8.1% between 2020 and 2025.

Commenting on the DCGI approval, **Mr. Manohar BN, MD & CEO of Stempeutics** said, "Obtaining DCGI approval for Stempeucel® is an important and historic milestone for Stempeutics. It is a strong recognition for Stempeutics for its sustained excellence of scientific and clinical work and underscores our 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."

**Mr. Umang Vohra, Managing Director and Global CEO of Cipla**, said, "Our focus on innovation is guided by our strong sense of responsibility to address unmet patient needs and alleviate suffering. We are pleased to see that our decade-long partnership with Stempeutics has achieved a significant milestone. CLI is a serious and painful condition that impacts patients worldwide and we are happy that we are able to introduce this stem cell therapy in the country at an affordable cost."

**Dr Pawan Kumar Gupta, Senior VP, Medical & Regulatory Affairs, Stempeutics**, said, "We are excited to receive this marketing approval from DCGI for this very important indication. In CLI, fatty deposits block arteries in the leg, leading to greatly reduced blood flow, pain at rest, non-healing ulcers, and gangrene. Patients with CLI are at an immediate risk for limb amputation and death. Now Stempeucel® provides hope for a new, effective treatment and a better quality of life for such CLI patients. Also, Stempeutics is committed to advancing its peripheral artery disease programs in CLI to other parts of the World."

#### **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 cell therapy drugs addressing major unmet medical needs with India first global next approach.

**About Cipla:**

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 46 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3<sup>rd</sup> largest in pharma in India (IQVIA MAT June'20), 3<sup>rd</sup> largest in the pharma private market in South Africa (IQVIA MAT June'20), and is among the most dispensed generic players in the U.S. For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit [www.cipla.com](http://www.cipla.com), or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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