Stempeutics receives U.S. Patent 12,661,377 for treatment of Osteoarthritis using Stempeucel®-OA followed by a single injection of Hyaluronic Acid

- *Patent covers administration of a single dose of 25 million ex vivo expanded, pooled, cultured adult human bone marrow-derived mesenchymal stromal cells (Stempeucel®-OA) followed by a single injection of mid-molecular-weight hyaluronic acid*
- *Stempeucel®-OA received marketing approval from India's Central Drugs Standard Control Organisation (CDSCO) and is marketed under the brands CiploStem by Cipla and StemOne by Alkem*
- *More than 1,000 patients have been treated with Stempeucel®-OA to date*
- *The therapy has completed Phase 3 clinical evaluation in 146 patients in India, with WOMAC Composite index showing 71.43% improvement in the cell arm over placebo at 24 months*
- *Phase 3, 12-month data have been published in the American Journal of Sports Medicine and 24-month data have been published in Osteoartirtis and Cartilage Open*

Bengaluru, August 12th, 2026: Stempeutics Research, a group company of Manipal Education and Medical Group, today announced that the United States Patent and Trademark Office (USPTO) has granted **U.S. Patent No. 12,661,377** for a treatment approach using its stem cell-based drug Stempeucel®-OA for osteoarthritis on 23rd June 2026. The patent covers an ultrasound-guided, intra-articular treatment involving a single dose of 25 million ex vivo expanded, pooled and cultured adult bone marrow-derived mesenchymal stromal cells (Stempeucel®-OA), administered before a single injection of mid-molecular-weight hyaluronic acid. The therapy is intended to act at the cellular level, helping reduce inflammation and pain, improve joint function and support the preservation of cartilage quality in patients with Grade II and III knee osteoarthritis.

The patented invention also covers methods associated with increasing levels of anti-inflammatory markers and decreasing levels of disease-progression markers in individuals with osteoarthritis. The development addresses a significant and growing clinical need, with an estimated 48.4 million people in India living with knee osteoarthritis in 2021. As the condition can progressively affect mobility, physical function and quality of life, treatment approaches aimed at addressing the underlying disease process remain an important area of clinical research.

Commenting on the U.S. patent, Dr Sudarshan Ballal, Chairman of Stempeutics, said, *"The patent granted by the USPTO is a strong recognition of Stempeutics' sustained excellence in scientific and clinical research and underscores our global leadership in allogeneic, pooled MSC technology. We believe that Stempeucel®-OA is a game-changer, offering an advanced therapeutic treatment for millions of patients suffering from osteoarthritis."*

Mr Manohar BN, MD & CEO of Stempeutics, said, *"Our focus on innovation is guided by our strong sense of responsibility to address unmet patient needs in India and alleviate suffering. Obtaining a U.S. patent for Stempeucel®-OA is an important and historic milestone for Stempeutics. We have always focused on developing therapies that fundamentally address disease. Stempeucel®-OA sets a new benchmark in regenerative medicine, reflecting years of dedicated research and robust Phase 3 evidence. We are happy to see the reach of this stem cell therapy across hospitals in India, transforming scientific innovation into tangible patient impact."*

The patent builds on Stempeutics' clinical development of Stempeucel®-OA for knee osteoarthritis, including a Phase 3 clinical study involving 146 patients. The study evaluated primary end point WOMAC composite index which showed statistically significant improvement of 71.43% compared to placebo ($p<0.0001$). The study also demonstrated statistically significant improvements on secondary end points - WOMAC pain, WOMAC stiffness and WOMAC physical function. Cartilage quality is maintained well as evidenced by MRI T2 mapping. Improvements were also observed in pro-inflammatory marker hsCRP, anti-inflammatory marker IL-10 & improvement in cartialge degradation marker CTX II (urine) in the Stempeucel®-OA Product arm.

The U.S. patent adds to Stempeutics' intellectual property portfolio covering its stem cell technology and clinical applications. The company has filed more than 100+ patents and received over 60+ granted patents globally including US, Japan and EU. Stempeucel® novel pooling technology manuscript has been published in Nature Scientific Reports. Stempeutics has already licensed the technology/product for Chronic Limb Threatening Ischemia indication in Japan and plans to expand similar licensing options for Osteoarthritis indication in Japan and globally.

About Stempeutics:

Stempeutics is a leading regenerative medicine company in India, with CDSCO (Indian FDA-equivalent)-approved and marketed cell-based therapeutic products under the Stempeucel® platform for three clinical indications. Published data from Phase 1, Phase 2, Phase 3 and Phase 4 trials demonstrate that Stempeucel® products are disease-modifying, with a single administration resulting in clinically meaningful efficacy and durable outcomes. Beyond its approved products, Stempeutics' pipeline comprises three additional Stempeucel® products in late- and early-stage human clinical trials. Founded in 2006, Stempeutics is built on innovative stem cell research originating from Manipal Education and Medical Group (MEMG), which culminated in the development of its proprietary Stempeutics Pooling Technology™, supported by nearly 100 issued patents and filed patent applications worldwide. The technology enables the robust, scalable, cost-effective and industrialised manufacture of Stempeucel® products with consistent biological activity and product potency. Stempeutics has marketing partnerships with Cipla and Alkem for the sale and distribution of its products in India and has also licensed its technology and products for commercial development and marketing in multiple countries outside India. The company continues to advance its technology platform to customise the biological activity of its therapeutic products for future bespoke clinical indications through further engineering of pooled donor-derived mesenchymal stromal cells.

For more information, please visit www.stempeutics.com

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