Stempeutics' cell therapy shows sustained benefit in knee osteoarthritis study

The peer-reviewed results, published in Osteoarthritis and Cartilage Open, showed statistically significant benefits over placebo across clinical, structural and biomarker outcomes, supporting the therapy's potential as a disease-modifying treatment.

New Delhi: Stempeutics on Tuesday said its cell therapy product Stempeucel-OA has shown sustained clinical benefits and cartilage preservation over 24 months in patients with knee osteoarthritis, according to results from a Phase 3 clinical study published in a peer-reviewed journal.

The 24-month efficacy and safety data from the randomized, double-blind, placebo-controlled Phase 3 trial have been published in Osteoarthritis and Cartilage Open, the company said in a statement.

According to the published findings, a single intra-articular injection of Stempeucel-OA led to statistically significant and durable improvements in pain and physical function compared with placebo, indicating the therapy's potential as a disease-modifying treatment for knee osteoarthritis.

The study reported significant improvement in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) composite score as well as all individual sub-scores in patients treated with Stempeucel-OA compared to placebo ($p < 0.0001$).

On structural outcomes, cartilage assessment using T2 mapping showed no worsening of cartilage in the medial femorotibial compartment in the treatment group, while patients receiving placebo showed progressive cartilage degeneration ($p < 0.0001$). The study also reported an increase in cartilage volume over time in the Stempeucel-OA group.

Biomarker analysis showed a significant reduction in urinary C-terminal cross-linked telopeptide of type II collagen (uCTX-II), a marker of cartilage degradation, in the Stempeucel-OA group, while levels increased in the placebo arm at Days 90 and 730 ($p < 0.0001$), the company said.

The 12-month results from the same Phase 3 study were earlier published in the American Journal of Sports Medicine in 2023.

Stempeutics said Stempeucel-OA is commercially available in India through marketing partnerships with Alkem Laboratories under the brand name StemOne and with Cipla under the brand name CiploStem, and is accessible across major hospitals.

Commenting on the findings, Dr Joe Joseph Cherian, Professor and Head of Orthopaedics at St John's Medical College Hospital, Bengaluru, and a Phase 3 investigator, said the two-year follow-up data highlight the potential of allogeneic cellular therapy to address unmet needs in knee osteoarthritis, especially among younger patients.

"Based on the Phase 3 data, Stempeucel-OA demonstrates durable pain reduction, improvement in physical function and quality of life, and the potential to preserve cartilage and slow disease progression in patients with Grade 2 and Grade 3 osteoarthritis," Cherian said.

Dr Nikhil Verma of Rush University Medical Center, Chicago, said the results could open new directions for cell-based regenerative therapies in the coming decade. He added that the therapy's ability to secrete pro-chondrogenic factors such as thrombospondin-2 may provide a mechanistic explanation for the observed clinical and structural benefits.

Stempeutics President for Medical and Regulatory Affairs, Dr Pawan Gupta, said osteoarthritis is among the most common and debilitating age-related conditions, affecting an estimated 30 million people in India.

"Current treatment options largely provide temporary symptom relief without altering disease progression. Stempeucel-OA has the potential to deliver durable symptom improvement while preserving cartilage and slowing disease progression in patients with Grade 2 and Grade 3 osteoarthritis," Gupta said.

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