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MEDIPOST treats first US participant in Phase III stem cell therapy trial

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The pivotal study is evaluating an allogeneic umbilical cord blood-derived MSC therapy for symptomatic cartilage defects due to knee osteoarthritis.

MEDIPOST

MEDIPOST has treated the first U.S. participant in its Phase III clinical trial evaluating an investigational mesenchymal stem cell therapy for symptomatic cartilage defects due to knee osteoarthritis.

The therapy is an allogeneic, umbilical cord blood-derived stem cell product being developed for inflammation-driven and degenerative disease. The U.S. trial marks an important regulatory and clinical step for MEDIPOST as it seeks to bring its regenerative medicine platform into the U.S. market.

Knee osteoarthritis affects more than 32 million adults and creates a treatment gap between non-interventional palliative care and total knee replacement. Many patients with cartilage defects experience pain, reduced mobility and declining quality of life, but may not yet be suitable for joint replacement.

The Phase III trial is enrolling adults aged 18 to 75 with knee cartilage lesions and osteoarthritis. It is designed to evaluate the clinical efficacy of the investigational MSC therapy and its potential benefit in adults with symptomatic cartilage defects.

The FDA has agreed that this single pivotal study, supported by confirmatory evidence from prior Phase III studies in South Korea and Japan, as well as Korean real-world evidence, can serve as the basis for MEDIPOST's planned U.S. Biologics License Application filing.

This regulatory alignment is important because regenerative medicine products often face complex evidence requirements. Prior clinical and real-world evidence from other markets may help support the U.S. development package if the pivotal study confirms efficacy and safety.

MEDIPOST has experience in the field through CARTISTEM, which it describes as the world's first approved allogeneic human umbilical cord blood-derived MSC therapy for knee osteoarthritis. The product was commercialised in South Korea in 2012, and more than 36,000 patients have received it there since launch.

The U.S. therapy remains investigational and has not been approved by the FDA. Its clinical benefit has not yet been established in the U.S. trial.