BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

MEDIPOST Secures FDA Agreement for CARTISTEM Phase III Strategy in US

June 10, 2026 | News

The agreement allows MEDIPOST to pursue a single pivotal Phase III study with confirmatory evidence, potentially accelerating its US BLA filing pathway.

MEDIPOST has secured FDA agreement to conduct a single pivotal Phase III study for CARTISTEM in the US, marking an important regulatory step for its knee osteoarthritis cell therapy programme.

This is significant because knee osteoarthritis remains a high-burden condition with limited disease-modifying treatment options. Many patients eventually progress toward more invasive procedures, creating demand for therapies that can support cartilage repair and delay worsening disease.

CARTISTEM is an allogeneic human umbilical cord blood-derived mesenchymal stem cell therapy for knee osteoarthritis. MEDIPOST describes it as the world's first regulatory-approved allogeneic hUCB-MSC therapy product for knee osteoarthritis, with commercial use in South Korea since 2012.

The FDA agreement allows MEDIPOST to support its US filing strategy with a single pivotal Phase III study and confirmatory evidence. This includes previous Phase III data from South Korea and Japan, as well as South Korea real-world evidence from around 550 patients treated at least three years ago.

This may reduce the overall US clinical development timeline and cost, while bringing the company closer to an earlier BLA filing pathway. MEDIPOST is also targeting patients in both the US and Canada, making North America a key part of its global commercialisation strategy.

However, adoption will depend on the eventual Phase III outcome, FDA review, payer assessment, manufacturing scalability and physician confidence in cell therapy use for osteoarthritis. Real-world evidence may help, but US regulators and payers will still require strong proof of clinical benefit and durability.

The agreement reflects growing regulatory openness to using international clinical data and real-world evidence where appropriate. For regenerative medicine companies, this could become an important pathway to make advanced therapies more efficient to develop and commercialise.