

Kolon TissueGene Reports Topline ACTiVION-II Phase 3 Clinical Trial Results for TissueGene-C (TG-C) Targeting Osteoarthritis (OA) of the Knee

- ACTiVION-II, the first of two U.S. Phase 3 clinical trials, did not meet the co-primary endpoints of VAS pain score and WOMAC® total score at Month 12.
- Results from ACTiVION-I, the second Phase 3 trial of TG-C targeting osteoarthritis (OA) of the knee, are anticipated in October 2026.
- Kolon TissueGene will further analyze the complete ACTiVION-II data.

ROCKVILLE, MD., July 20, 2026 /PRNewswire/ -- Kolon TissueGene, Inc. ("the Company") (KOSDAQ: 950160), a biotechnology company developing novel advanced cell therapies for orthopedic diseases and other unmet medical needs, today announced topline results from the first of two US Phase 3 clinical trials of TG-C, a potential first-in-class cell and gene therapy targeting osteoarthritis of the knee (OAK). The Phase 3 ACTiVION-II study ([NCT03291470](#)) evaluated the efficacy and safety of a single intraarticular injection of TG-C versus placebo in patients with Kellgren–Lawrence (KL) Grade 2 or 3 OAK.

The Phase 3 ACTiVION-II study enrolled 531 randomized subjects across 27 U.S. clinical trial sites. TG-C did not demonstrate statistically significant improvements versus placebo in pain and function, and did not meet the co-primary endpoints of change from baseline in VAS (Visual Analogue Scale) pain and WOMAC® (Western Ontario and McMaster Universities Osteoarthritis Index) total score at Month 12. Additionally, the study did not meet any of the key secondary endpoints.

TG-C was generally safe and well-tolerated with no new or unexpected safety signals identified. The overall incidence, severity, and pattern of treatment emergent adverse events were comparable between the TG C and placebo groups, with the majority of events reported as Grade 1 or Grade 2 in severity. The observed safety findings were consistent with the known safety profile of TG C and did not indicate any clinically meaningful safety concerns.

"While we are disappointed by the results from the first of two Phase 3 clinical trials of TG-C, we remain committed to advancing cell and gene therapy innovation targeting osteoarthritis of the knee," said Moon Jong Noh, PhD, Co-CEO of Kolon TissueGene.

Co-CEO of Kolon TissueGene, Seng Ho Jeon added, "We are deeply grateful to the study participants, investigators and clinical trial sites for their contributions to the ACTiVION-II study over the last several years. We continue to analyze the full data set for additional insights and anticipate reporting results from the second Phase 3 clinical trial of TG-C in October 2026."

Topline results from ACTiVION-I, the second Phase 3 clinical trial of TG-C ([NCT03203330](#))

targeting OA in the knee, are anticipated in October 2026, after which Kolon TissueGene will determine next steps.

About Kolon TissueGene, Inc.

Kolon TissueGene, Inc., is a clinical stage biotechnology company developing first-in class cell and gene therapy candidates utilizing its cell-gene platform technology. The Company's lead product, TG-C, is an allogeneic cell and gene therapy candidate being evaluated in a Phase 3 clinical program, comprising two Phase 3 clinical trials, in the US under a Special Protocol Assessment (SPA) agreement reached with the US FDA. For additional information about Kolon TissueGene, Inc., please visit www.tissuegene.com.

About TG-C

TG-C is a first-in-class cell and gene therapy targeting OA of the knee through a single intraarticular injection. As an allogeneic (off-the-shelf) therapy, TG-C could provide an alternative to traditional treatment and surgery, or delay the progression of OA to minimize the need for multiple surgical interventions. Phase 2 clinical trials held in the US have demonstrated pain relief and increased mobility, as well indicators towards decreased progression of OA and improvements in joint structure. In a concluded US Phase 2 clinical trial, TG-C also demonstrated a two-year improvement of pain and function. TG-C is being evaluated in a Phase 3 program comprising two Phase 3 clinical trials.

SOURCE Kolon TissueGene, Inc.

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