

KOLON TISSUEGENE HIGHLIGHTS LONG-TERM SAFETY DATA AND POTENTIAL U.S. FDA PATHWAY FOR TG-C AT OARSI WORLD CONGRESS

- THE WORLD'S MOST PRESTIGIOUS OSTEOARTHRITIS SOCIETY (OARSI) HELD FOR THE FIRST TIME IN KOREA
- LONG-TERM SAFETY DATA FROM OVER 15 YEARS SUPPORT THE SAFETY PROFILE OF TG-C, WITH PRELIMINARY SIGNS OF POTENTIAL EFFICACY BENEFITS

ROCKVILLE, Md., April 28, 2025 /PRNewswire/ -- Kolon TissueGene participated in the 2025 Osteoarthritis Research Society International (OARSI) World Congress on Osteoarthritis, which took place in Songdo, South Korea, from April 24-27, 2025. This year marked the first time the globally prestigious osteoarthritis society hosted its annual congress in Korea. During the event, Kolon TissueGene presented new long-term data supporting the safety and efficacy of its investigational therapy, TG-C — the world's first cell and gene therapy for osteoarthritis — while highlighting its potential for U.S. FDA approval.

On April 25, Kolon TissueGene delivered a presentation titled "*TG-C, the First Potential DMOAD^{*1} Therapy: Intra-Articular Cell-Based Gene Therapy with Long-Term Safety and Insight into Delaying Total Knee Arthroplasty (TKA)*". The presentation focused on TG-C's long-term safety profile and its potential to delay total knee arthroplasty (TKA), using long-term follow-up data (US LTS) as a basis.

The study included data from 33 subjects who participated in the U.S. Phase 2 trial and 110 subjects from the Phase 3 trial who completed two years of follow-up. The ongoing Phase 3 trial data were analyzed in a blinded manner, including both TG-C and placebo arms, allowing for an objective evaluation of the long-term safety and treatment effects.

Safety Results: No treatment-related tumor cases were reported in TG-C enrolled subjects during nearly 15 years of long-term clinical observation in the United States. Moreover, age-specific cancer incidence among TG-C subjects consistently showed lower rates compared to the general U.S. population, based on SEER (Surveillance, Epidemiology, and End Results) data from the U.S. National Cancer Institute — a compelling indicator of TG-C's safety.

Efficacy Results: Kolon TissueGene also presented data comparing the rate and timing of knee replacement surgery among TG-C–treated subjects versus the broader osteoarthritis population^{*2} in the U.S. According to the Osteoarthritis Initiative (OAI), which includes 11 years of longitudinal data sponsored by the U.S. National Institutes of Health (NIH), 15.5% of 595 patients meeting TG-C–eligible criteria underwent TKA at a median of 5.1 years after osteoarthritis onset.

In contrast, only 7.0% of TG-C–treated subjects underwent TKA, with the median time to surgery extended to 5.7 years. These findings suggest that TG-C may either replace or significantly delay the need for surgical intervention — a hallmark of a disease-modifying osteoarthritis drug (DMOAD). The data supports TG-C's potential to slow structural progression of osteoarthritis and offers a meaningful therapeutic alternative.

Executive Commentary: Dr. Moon Jong Noh, Co-CEO of Kolon TissueGene, stated, "We are honored to share meaningful TG-C data at the first-ever OARSI congress held in Korea. This opportunity reinforces our optimism for FDA approval and recognition of TG-C as the world's first DMOAD therapy." Co-CEO Seng Ho Jeon, who joined the company in March, added, "The scientific data presented strongly supports the safety and efficacy of TG-C. We are pursuing parallel strategies for both regulatory approval and commercialization to establish TG-C as a global blockbuster treatment."

About OARSI: Headquartered in New Jersey, USA, the Osteoarthritis Research Society International (OARSI) is the world's leading organization for scientists and healthcare professionals working in the field of osteoarthritis prevention and treatment. Each year, the society holds its global congress in major cities worldwide, drawing over 1,500 experts from more than 50 countries, including clinical researchers, orthopedic specialists, radiologists, and physical therapists.

About TG-C: TG-C is the world's first cell and gene therapy developed for knee osteoarthritis and is classified as a first-in-class investigational drug. It is currently undergoing follow-up in a U.S. Phase 3 trial following completion of dosing. As of 2024, the osteoarthritis market in the seven major countries (U.S., France, Germany, Italy, Spain, U.K., and Japan) is estimated at KRW 3.8 trillion, with a projected compound annual growth rate of 5.3%, reaching KRW 5.5 trillion by 2031. The global market is expected to exceed KRW 12 trillion. Currently dominated by low-cost analgesics, the introduction of effective disease-modifying therapies like TG-C could significantly expand market potential. (Source: GlobalData, Osteoarthritis: Epidemiology Forecast to 2031, June 17, 2022)

*(*1) Disease-Modifying Osteoarthritis Drug*

*(*2) Data from the Osteoarthritis Initiative (OAI), a large-scale, public, long-term follow-up study sponsored by the U.S. National Institutes of Health (NIH).*

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