

U.S. CLINICAL PROGRESS

CARTISTEM® Advances in its North American Phase 3 Clinical Trial

The first U.S. participant has been treated; the study is registered on ClinicalTrials.gov.

Prepared by St. Luke Hospital · Based on the manufacturer's announcement published via PR Newswire, 8 July 2026.

Focus: Current status of the U.S. Phase 3 programme.

Key points

- **First U.S. participant treated:** The manufacturer reported in July 2026 that the first participant in the U.S. Phase 3 trial had been treated.
 - **Study population:** Adults aged 18–75 with symptomatic cartilage defects due to knee osteoarthritis.
 - **Trial registration:** The study is registered on ClinicalTrials.gov under identifier NCT07339111, where the protocol, eligibility criteria and participating sites are published.
 - **Purpose of the study:** The trial is intended to support a future Biologics License Application, alongside data from the Korean and Japanese programmes.
- **What this does not mean:** An ongoing clinical trial is not the same as an available treatment. CARTISTEM® is not approved for commercial use in the United States, and enrolment in a trial is decided by the trial sites, not by St. Luke Hospital.

Original source

Manufacturer announcement (PR Newswire, 8 July 2026)

Trial record: ClinicalTrials.gov NCT07339111

Regulatory notice. CARTISTEM® is approved in the Republic of Korea (MFDS, January 2012). It is **not approved for commercial use in the United States or in Japan**, where it remains under clinical investigation. Progress in clinical development does not indicate that regulatory approval will be granted. **Medical information notice.** This summary is provided for general information and does not replace an in-person medical consultation, diagnosis, or treatment recommendation. Treatment at St. Luke Hospital is provided within the Korean approved indication, following an individual orthopedic assessment. Outcomes vary between patients.