

CLINICAL TRIAL RESULTS

CARTISTEM® Met All Primary and Secondary Endpoints in the Japan Phase 3 Trial

Statistically significant results versus hyaluronic acid on knee pain, knee function, and cartilage defect grade.

Prepared by St. Luke Hospital · Based on the manufacturer's announcement, 13 May 2026.

Focus: Reported outcomes on joint function (WOMAC) and cartilage defect grade (ICRS).

Key points

- **Study design:** A randomized controlled study in 130 participants (59 CARTISTEM®, 61 hyaluronic acid control) across 13 sites in Japan, with a 52-week follow-up period. Mean age was 61.3 and 62.2 years respectively, with balanced baseline characteristics.
 - **Primary endpoints met:** WOMAC pain and function index ($p < 0.0001$) and ICRS cartilage defect grade ($p = 0.0002$).
 - **Secondary endpoints met:** VAS pain intensity, IKDC and KOOS knee function scores, and the WOMAC pain, function and stiffness subscales (all $p < 0.0001$).
 - **Safety reported in the study:** The manufacturer reported that all serious adverse events recorded during the study were assessed as having no causal relationship to CARTISTEM®.
- **What this does not mean:** Trial results describe outcomes observed in a defined study population under study conditions. They do not predict the result of treatment in any individual patient. CARTISTEM® is not approved for commercial use in Japan.

Original source

Manufacturer announcement (MEDIPOST, 13 May 2026)

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.