

The Drugs Controller General (India)

The Directorate General of Health Services; Ministry of Health and Family Welfare; Government of India

FDA Bhawan, Kotla Road; New Delhi – 110 002

Subject: Report of Serious Adverse Event (SAE) of injury under the clinical trial protocol No: KORTUC Protocol-Regarding:

Protocol Title: Randomised phase II trial testing efficacy of intra-tumoural hydrogen peroxide a radiation sensitiser in patients with locally advanced/recurrent breast cancer- CCR5119 KORTUC

Subject No: 07/5119/023

Date of Onset: 19 Apr 2026

Date of Resolution: 20 Apr 2026

CTRI Regd. No: CTRI/2022/02/040331

Adverse Event: Abdominal Distension

Causality: Unrelated to the trial intervention

Outcome: Resolved/ Discharged

Severity: Grade III

Brief History:

☐ 13-SEP-2024: Completed palliative radiotherapy (36 Gy in 6 fractions) to the left breast under the standard arm initiated on 27-AUG-2024.

☐ 19-APR-2026:

o Admitted under the Medical Oncology team for management of abdominal distention, nausea, constipation, and left lower limb swelling.

o Underwent bilateral lower limb USG Doppler, which ruled out deep vein thrombosis (DVT) and identified mild diffuse subcutaneous edema.

o Performed therapeutic ascitic tapping and administered intravenous Human Albumin and Metoclopramide as part of the inpatient supportive care regimen.

☐ 20-APR-2026: Discharged in stable condition following clinical stabilization and symptomatic relief.

SAE subcommittee decision:

☐ Time relationship: Appropriate

☐ Competing Causes: None

☐ De-Challenge/ Re-challenge: NA

☐ WHO-UMC Causality: Unlikely

IRB Decision: The patient was in the standard arm. It is unlikely that the current SAE is related to the trial intervention.

Financial compensation: Not Applicable for compensation and medical management

Sincerely,

Dr Indranil Mallick

Member Secretary;

Institutional Review Board; Tata Medical Center; Kolkata 700160