

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: 07/5119/029

Date of Onset: 29 Mar 2026

Date of Death: 29 Mar 2026 [Notified to IRB on 22 Apr 2026]

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

Adverse Event: Myocardial infarction

Causality: Unlikely to be related to the trial intervention

Outcome: Death

Severity: Grade V

Brief History:

- ☐ 20-SEP-2025:
 - o Completed palliative radiotherapy (36 Gy in 6 fr) for metastatic carcinoma of the left breast.
 - o Exemestane therapy initiated following documented disease progression during the post- radiotherapy surveillance period.
- ☐ 15-MAR-2026: Transitioned to best supportive care under a palliative team due to escalating respiratory distress and a significant decline in performance status, which precluded further active oncological intervention.
- ☐ 29-MAR-2026: The patient passed away at 06:05 AM; the immediate cause of death recorded on the death certificate by local physician > acute coronary syndrome.
- ☐ 06-APR-2026: Trial site notified of the patient's death. The delay in reporting was due to the family not proactively informing the study team at the time of the event.

SAE subcommittee decision:

- ☐ Time relationship: Appropriate
- ☐ Competing Causes: Disease progression
- ☐ De-Challenge/ Re-challenge: NA
- ☐ WHO-UMC Causality: unlikely to be related to trial

IRB Decision: The patient had further disease progression and likely died as a result of the progressive disease. The cause of death was deemed to be ACS. No compensation is recommended.

Financial compensation: Not Applicable for compensation and medical management

2. Indicate with justification and documentary evidence as to whether the SAE (injury) is related/not related to each of the following criteria:

- Adverse effect of investigational product(s): No
- Violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or investigator: No
- Failure of investigational product to provide intended therapeutic effect [where the standard care, though available, was not provided to the subject as per the clinical trial protocol]: No
- Use of placebo in a placebo-controlled trial [where, the standard of care, though available, was not provided to the subject as per the clinical trial protocol]: No
- Adverse effect due to concomitant medication excluding standard of care necessitated as part of approved protocol: No
- For injury to a child in-utero because of the participation of present in clinical trial: No
- Any clinical trial procedure involved in the study: No

3. Risk Factor Assessment (0.5 to 4) as per the compensation formula decided by IEC: NA

Sincerely,

Dr Indranil Mallick

Member Secretary;

Institutional Review Board; Tata Medical Center; Kolkata 700160