

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 71 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year 06 JAN 2024	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Metastasis/Balls found in the brain of great importance/loss of strength in hands/ shoulder pain/ back pain/ arm pain/trouble walking [Malignant neoplasm progression] Red ball in the same place where she underwent surgery [Mass] Body ache [Pain] felt down [Depressed mood] did not want fluids [Thirst decreased] Itching [Pruritus] Redness [Erythema] Skin outbreak, in areas in the groin and waist [Rash]							<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input checked="" type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input checked="" type="checkbox"/> LIFE THREATENING

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Tablet	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 150 mg, bid	16. ROUTE(S) OF ADMINISTRATION #1) Oral
17. INDICATION(S) FOR USE #1) breast cancer (Breast cancer)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 02-JAN-2024 / Ongoing	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown	Type of History / Notes Medical Condition left side Procedure	Description Lymphedema (Lymphoedema) Mastectomy (Mastectomy)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Eli Lilly Interamerica Inc (AR Branch) Tronador 4890 - Piso 12 Buenos Aires, Capital Federal CP: 1430 ARGENTINA Phone: 54 1145464000	26. REMARKS	
24b. MFR CONTROL NO. CR202401007442	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.	
24c. DATE RECEIVED BY MANUFACTURER 11-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 17-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

17-Jun-2025 11:24

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Dehydrated [Dehydration]
Sciatic type pain, burning pain [Pain]
numbness [Hypoaesthesia]
severe pain in her left arm [Pain in extremity]
burning sensation [Burning sensation]
Diarrhea [Diarrhoea]
did not eat [Decreased appetite]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 71-year-old (at the time of initial report) female patient of an unknown origin.

Medical history included left mastectomy and lymphedema in the arm on the same side and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice daily via oral route for the treatment of breast cancer, beginning on 02-Jan-2024. On 06-Jan-2024, she had moderate diarrhea, felt down, did not eat, did not want fluids and was somewhat dehydrated. She had not consulted with her treating physician, so she was advised to seek medical attention if she worsens. On 29-Mar-2024, she presented with sciatic type pain, described it as a burning pain and with an intensity of 5/10, as a corrective treatment she received unspecified analgesics without prescription. On 01-Oct-2024, she had skin outbreak in areas in the groin and waist, brown and sometimes turned reddish and sometimes itchy. In Mar-2025, she had severe pain in her left arm and associated with numbness and burning sensation to the touch. She went several times to the emergency room and treated with analgesics, the pain subsided for a while, but then continued with the same intensity. And despite various oral analgesics the pain persisted. On 06-Apr-2025, she had red ball in the same place where she underwent surgery due to which she was hospitalized. The event mass was considered as serious by the reporter due to life threatening and disability/incapacity. On 15-Apr-2025, she had trouble walking. On 20-Apr-2025, she had shoulder pain and back pain due to which she was hospitalized. Since May-2025, she experienced severe pain in her back, arm and body due to which she was hospitalized and received morphine as corrective treatment. On 13-May-2025, she experienced loss of strength in hand and balls found in the brain of great importance due to which she was hospitalized. The pain was thought to be muscular, but it spread to her shoulder and back after performing a computerized tomography scan (CT) was performed. On 20-May-2025, she was diagnosed with metastasis due to which she was hospitalized. The event malignant neoplasm progression considered as serious by the reporter due to life threatening, disability/incapacity and causes hospitalization (or prolongs hospitalization). Additionally, there was a change in her blood tests (but it was unspecified). Information regarding the corrective treatment for remaining events was not provided. Outcome of the event pain was recovering and of remaining events was not resolved and abemaciclib therapy was continued.

The initial reporting consumer related the events of pain and mass, did not relate the event of malignant neoplasm progression whereas did not provide relatedness assessment of the remaining events with abemaciclib therapy.

Update 21-Mar-2024: Information received from local affiliate on 20-Mar-2024. Business partner confirmed that permission to contact HCP was not granted hence follow up not possible with the HCP. No medically significant information received.

Update 04-Apr-2024: Information received from the initial reporter via business partner on 01-Apr-2024. Added one non-serious event of pain. Updated case and narrative accordingly with new information.

Update 21-May-2024: Information received from the initial reporter via business partner on 15-May-2024. No medically significant information received.

Update 30-Oct-2024: Additional information from the initial reporter via PSP was received on 25-Oct-2024. Added three non serious events of pruritus, rash and erythema. Updated narrative with new information.

Update 24-Apr-2025: Additional information received from the initial reporter via business partner on 16-Apr-2025. Added two medical history of mastectomy and lymphedema, three non-serious event of Numbness, Pain in arm and Burning sensation. Updated case and narrative accordingly with new information.

Update 03-Jun-2025: Additional information received from the initial reporter via business partner on 29-May-2025. The case was upgraded from non-serious to serious due to addition of serious events of back pain, pain and pain in extremity. Added morphine as treatment medication. Updated the narrative and causality statement with new information.

Update 17-Jun-2025: Additional information received from the initial reporter via business partner on 11-Jun-2025. This case was upgraded to P1 (life threatening) due to addition of two serious events of malignant neoplasm progression and mass. Updated the narrative with new information.

Lilly Analysis Statement: 17-Jun-2025: The company considered the events of diarrhea and appetite suppressed related to abemaciclib.

Lilly Company Assessment of Relatedness (17Jun2025): The company assessment is that the event of mass (red ball in the same

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

place where she underwent surgery) is not reasonably possibly related to because there is limited information on etiology, diagnostic details, and surgery performed; therefore, it is not possible to establish a relationship with this individual case