

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 71 Years	3. SEX Female	3a. WEIGHT 56.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☒ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☒ LIFE THREATENING
		Day	Month	Year			Day	Month	Year		
		PRIVACY					06	JAN	2024		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
Other Serious Criteria: med sig
Red ball in the same place where she underwent surgery / bright red, very prominent, about the size of a chickpea [Mass]
Metastasis/Balls found in the brain of great importance/ masses in the brain and lungs / loss of strength in hands/ shoulder pain/ back pain/ severe pain in her left arm / arm pain/trouble walking [Malignant neoplasm progression]
Body ache [Pain]
felt down [Depressed mood]
did not want fluids [Thirst decreased]

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Abemaciclib (Abemaciclib) Film-coated tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ 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? ☐ YES ☐ NO ☐ NA
18. THERAPY DATES(from/to) #1) 02-JAN-2024 / MAY-2025	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 APR-2023 to Ongoing Unknown	Type of History / Notes Medical Condition Medical Condition left side	Description Breast cancer (Breast cancer) Lymphedema (Lymphoedema)

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. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 15-JUL-2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:	
DATE OF THIS REPORT 18-JUL-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 5	

18-Jul-2025 10:27

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

Itching [Pruritus]
 Redness [Erythema]
 Skin outbreak, in areas in the groin and waist [Rash]
 Dehydrated [Dehydration]
 Sciatic type pain, burning pain [Pain]
 numbness [Hypoaesthesia]
 burning sensation [Burning sensation]
 heartburn [Dyspepsia]
 Diarrhea [Diarrhoea]
 did not eat [Decreased appetite]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) from a business partner, with additional information from the initial reporter via PSP and from another consumer in response to a medical questionnaire, concerned a 71-year-old (at the time of initial report) female patient of an unknown origin.

Medical history included left nipple mastectomy on 28-Apr-2023 and lymphedema in left arm and breast cancer from Apr-2023. Concomitant medications were not provided.

The patient received abemaciclib (Verzenio) coated tablet, 150 mg, twice daily, via oral, for the treatment of breast cancer, beginning on 02-Jan-2024. Concomitant chemotherapy if any was not provided. 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 experienced severe pain in her left arm which associated with numbness and burning sensation to the touch; she went several times to the emergency room and was treated with analgesics including boltaron (as reported), betamethasone, ibuprofen, acetaminophen, liquid acetaminophen (not sure), and codeine. She was taken to palliative care and the left arm pain subsided for a while but then continued with the same intensity, and despite various oral analgesics the pain persisted. Therefore, she was under observation and then she was hospitalized for consultation, and started giving her tramadol hydrochloride, but from the second day the tramadol hydrochloride stopped working and they sent her for morphine sulfate. On 06-Apr-2025, she had a red ball in the same place where she underwent surgery due to which she was hospitalized and in addition, this event was considered serious by the reporter due to life threatening, disability/incapacity and medically significant reasons. The red ball was bright red, very prominent, about the size of a chickpea. A biopsy was performed on the red lump and liver but still awaiting results. 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. The pain was thought to be muscular, but it spread to her shoulder and back after performing a computerized tomography scan (CT). 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. The body pain was also considered serious by the reporter due to medically significant reasons. 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. On 20-May-2025, she was diagnosed with metastasis due to which she was hospitalized, and in addition, this event was considered serious by the reporter due to life threatening, disability/incapacity and medically significant reasons. The following events were part of metastasis: balls in the brain, loss of strength in hands, spreading pain to shoulder and back, liver, severe pain in her left arm/arm pain and trouble walking. On an unknown date, there was a change in her blood tests (not specified). On an unknown date, she experienced heartburn for which took morphine tablet, metoclopramide and then morphine syrup as corrective treatment, but she continued with heartburn. On an unknown date in May-2025 or Jun-2025 (conflicting date provided), her abemaciclib therapy was discontinued. On 06-Jun-2025, she was hospitalized again; a CT scan was performed showing something strange and oncologist indicated that there was suspicion of metastasis as further unspecified tests performed found masses in the brain and lungs. She received three sessions of brain radiotherapy as corrective treatment for mass and metastasis and the mass on the left side of her brain was dead. After being hospitalized for eight days, she returned home on 14-Jun-2025. Information regarding further corrective treatments was not provided. She was recovering from body pain and was not recovered from the remaining events. Abemaciclib therapy was discontinued.

The initial reporting consumer related body pain and red ball to abemaciclib, did not relate metastasis and mass to abemaciclib, while did not provide relatedness assessment of the remaining events with abemaciclib therapy. The second reporting consumer did not provide causality for the events and 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

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

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.

Update 25-Jun-2025: Additional information was received on 20-Jun-2025 from another consumer in response to a medical questionnaire. Added the date of historical left mastectomy, added medical significance criteria to all serious events; following treatments: betamethasone, ibuprofen, acetaminophen, codeine, tramadol hydrochloride, morphine sulfate and metoclopramide; non-serious event of heartburn, CT scan and biopsy. Updated description reported for the red ball and malignant neoplasm progression, and narrative accordingly with new information.

Update 07-Jul-2025: Additional information received from the initial reporter via PSP conducted by a business partner, on 02-Jul-2025. Added patient medical history (breast cancer) and patient demographics (Height and weight). Updated action taken with abemaciclib therapy from ongoing to drug discontinued and narrative with new information.

Update 17-Jul-2025: Additional information received from the initial reporter via PSP conducted by a business partner, on 15-Jul-2025. Updated outcome of malignant neoplasm progression from unknown to not recovered, treatment received for malignant neoplasm progression and mass from unknown to yes. Updated causality as reported for mass from yes to no. Updated the narrative and causality statement with new information.

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

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

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Biopsy		
		biopsy was performed on the red lump and liver (she was still awaiting results).		
2		Computerised tomogram		
		saw something strange		
		suspicion of metastasis		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
28-APR-2023 to Unknown	Procedure	Mastectomy (Mastectomy); left nipple for breast cancer