SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		61 Years	Female	73.00 kg		JUN	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Low defenses [Decreased immune responsiveness]
No taste in food [Ageusia]
Nausea [Nausea]
1 diarrhea daily [Diarrhoea]
no appetite [Decreased appetite]

Case Description: This solicited case, reported by a consumer received via a patient support program (PSP) conducted by a business partner, concerned a 61-year-old female patient of an unknown origin.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Abemaciclib (Abemaciclib) Tablet

(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid	#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)	19. THERAPY DURATION
#1) 20-MAY-2025 / JUN-2025	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) CALCIUM (CALCIUM) Unknown ; Unknown
#2) VITAMIN D3 (VITAMIN D3) Unknown ; Unknown
#3) HYOSCINE (HYOSCINE) Unknown ; Unknown
#4) BROMID (BUTYLSCOPOLAMINE BROMIDE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown		

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.
CR202507004625

24c. DATE RECEIVED BY MANUFACTURER
11-JUL-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
16-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: CR202507004625

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history was not provided. Concomitant medications included calcium, vitamin D3, hyoscine and bromide

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice a day, via oral route, for the treatment of breast cancer beginning on 20-May-2025. On an unknown date in Jun-2025, her immune system was weakened, and she was given unspecified vitamin injections as corrective treatment. Her abemaciclib therapy was stopped for approximately three weeks or almost a month (as reported) due to the event. On an unknown date, she resumed her abemaciclib therapy. On 01-Jul-2025, she experienced nausea which was treated with dimenhydrinate. On an unknown date, she experienced diarrhea once a day, had no appetite, and no taste in food. The outcome of event immune system disorder was unknown whereas nausea was recovered and remaining events were not recovered. The abemaciclib therapy was temporarily discontinued, and then restarted and continued.

The initial reporting consumer related the events with abemaciclib therapy.

Update 16-Jul-2025: Additional information was received from the initial reporter on 11-Jul-2025. Added patient demographics weight, height, three non-serious event of diarrhea, taste loss and appetite decreased, added four concomitant medications calcium, vitamin D3, hyoscine and bromide and updated narrative with new information

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown