SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		78 Years	Female	Unk		MAR	2025

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
Venous thrombosis [Venous thrombosis]
Leg pain [Pain in extremity]
diarrhea [Diarrhoea]
Dizziness [Dizziness]
Tiredness [Fatigue]
Headache [Headache]
Her hair started to fall out [Alopecia]

Case Description: This solicited case, reported by a consumer via a **(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

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) 27-DEC-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)
#1) LETROZOLE (LETROZOLE) Unknown ; Unknown
#2) PROCTIS (BISMUTH SUBGALLATE, BUFEXAMAC, LIDOCAINE HY

(Continued on Additional Information Page)

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.
GT202501013172

24c. DATE RECEIVED BY MANUFACTURER
02-MAY-2025

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

DATE OF THIS REPORT
14-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient support program (PSP), with additional information from the reporting consumer, concerned a 78-year-old female patient of unknown origin.

Medical history was not provided. Concomitant medications included bismuth subgallate with bufexamac and lidocaine hydrochloride monohydrate for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily orally, for the treatment of breast cancer, beginning on 27-Dec-2024. As concomitant chemotherapy she received letrozole. On an unknown date, after starting abemaciclib therapy, she experienced dizziness, diarrhea that did not occur every day and she usually had three bowel movements on the days when she had diarrhea. She felt tired, with pain in her legs and some headache. On 10-Jan-2025, she had two to three diarrheal bowel movements per day. Approximately in Mar-2025 her hair started to fall out but was not very noticeable. On 14-Apr-2025, she was diagnosed with venous thrombosis in her right leg and prescribed unspecified anticoagulants and antibiotics as corrective treatment. Information regarding further corrective treatment was not provided. The outcome of all the events was not resolved. Therapy status of abemaciclib was continued.

The reporting consumer did not provide an opinion on relatedness assessment of the events with abemaciclib therapy.

Update 27-Jan-2025: Information was received on 21-Jan-2025. No new medically significant information was received and hence no changes were made to the case.

Update 09-May-2025: Additional information was received on 02-May-2025 from the reporting consumer via a PSP. This case was upgraded due to the addition of a serious event of venous thrombosis. Added a non-serious event of hair loss. Updated narrative with new information.

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) PROCTIS (BISMUTH SUBGALLATE, BUFEXAMAC, LIDOCAINE HYDROCHLORIDE MONOHYDRATE) Unknown ; Unknown