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	COSTA RICA		PRIVACY		65 Years	Female	66.00 kg		FEB	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
Thrombosis [Thrombosis]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), with additional information from the initial reporter, with additional information from the initial reporter, concerned a 65-year-old female patient of an unknown origin.

Medical history included breast cancer diagnosed in Mar-2023 and had an unspecified operation on 07-Jul-2023.

(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

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)

18. THERAPY DATES(from/to)
#1) 01-JUN-2024 / MAR-2025

19. THERAPY DURATION
#1) Unknown

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

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☐ NA

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	Type of History / Notes	Description
MAR-2023 to Ongoing	Medical Condition	Breast cancer (Breast cancer)
07-JUL-2023 to Unknown	Procedure	Operation NOS (Surgery)
	Unspecified surgery	

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.
CR202507006579

24c. DATE RECEIVED BY MANUFACTURER
06-AUG-2025

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

DATE OF THIS REPORT
12-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Concomitant medications included unspecified blood pressure pills.

The patient received abemaciclib (Verzenio) tablet, 150 mg at twice daily via oral route, for breast cancer, beginning on 01-Jun-2024. Information regarding concomitant chemotherapy was not provided. On an unspecified date at the end of Feb-2025, six or seven months after starting abemaciclib therapy, she experienced moderate thrombosis. As a corrective treatment she took apixaban, which would be taken until Sep-2025. The event of thrombosis was considered as serious by the reporter due to medically significant reason. Abemaciclib therapy was discontinued on an unknown date in Mar-2025. On an unknown date, she recovered from the event after discontinuation, and she had not resumed abemaciclib therapy again.

The reporting consumer related the event with abemaciclib therapy.

Update 21-Jul-2025: Information was received on 16-Jul-2025. No medically significant information was received. No changes were made to the case.

Update 01-Aug-2025: Additional information was received from the initial reporter in response to a medical questionnaire via PSP on 29-Jul-2025. Added apixaban as treatment medication. Updated onset date of the event of thrombosis, the outcome of the event of thrombosis from recovering to recovered and narrative with the new information.

Update 11-Aug-2025: Additional information received on 06-Aug-2025 from the initial reporter via a PSP. Added unspecified operation as medical history. Updated narrative accordingly.