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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	GUATEMALA		PRIVACY		74 Years	Female	Unk	22	APR	2025	

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

Patient administered half 150 mg at night; No AE [Wrong technique in product usage process]
Patient administered Verzenio 100 mg daily, No AE [Off label use]
Agitation [Agitation]
Fatigue [Fatigue]
Diarrhea [Diarrhoea]
Anemia [Anaemia]
Low red blood cell counts [Red blood cell count decreased]

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

(Continued on Additional Information Page)

- ☐ 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)
#1) 150 mg, bid

16. ROUTE(S) OF ADMINISTRATION
#1) Oral

17. INDICATION(S) FOR USE
#1) Metastatic Breast Cancer (Breast cancer metastatic)

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

18. THERAPY DATES(from/to)
#1) 21-DEC-2024 / MAR-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	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.
GT202505003624

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
09-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: GT202505003624

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient Support Program (PSP), concerned a 74-year-old female patient of an unknown origin.

Medical history and concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablet, at an 150 mg dose, twice daily, orally, for the treatment of metastatic breast cancer, beginning on 21-Dec-2024.On an unknown dose, she experienced discomfort at night with tiredness and agitation. On an unknown date in Mar-2025, dose of abemaciclib was decreased to 225 mg (150 mg in morning and half 150 mg at night) (wrong technique in drug usage process). On 22-Apr-2025, she had lab tests done which showed anemia and low red blood cell counts due to which dose of abemaciclib was decreased to 150 mg once daily (Off label use). Additionally she experinced diarrhea. Information regarding corrective treatment included loperamide hydrochloride for diarrhea and not provided for rest of events. Outcome of the events was not reported for off label use, wrong technique in drug usage process and not recovered for remaining events. The status of abemaciclib therapy was ongoing.

The reporting consumer did not provide an opinion on relatedness with abemaciclib therapy.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	22-APR-2025	Red blood cell count decreased Low red blood cell counts(no results, reference range nor units provided)		

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	225 mg, bid (150 mg in morning and half 150 mg at night); Oral	Metastatic Breast Cancer (Breast cancer metastatic)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #3	150 mg, daily; Oral	Metastatic Breast Cancer (Breast cancer metastatic)	Ongoing; Unknown