CIOMS FORM

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	06	FEB	2025	

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

Fatigue that makes movement impossible [Fatigue]
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]
Low defenses [Decreased immune responsiveness]
Lack of oxygen [Oxygen saturation decreased]
Diarrhea [Diarrhoea]
Anemia [Anaemia]
Low red blood cell counts [Red blood cell count decreased]

(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)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid	#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)	19. THERAPY DURATION
#1) 21-DEC-2024 / MAR-2025	#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
26-JUN-2025

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

DATE OF THIS REPORT
08-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: GT202505003624

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This solicited case, reported by a consumer via a 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. As of 26-Jun-2025, her fatigue made her movement impossible, therefore it was considered as serious by the reporter due to disability or incapacity significant or persistent. On 06-Feb-2025, she had experienced mild lack of oxygen and was ordered an echocardiogram, which was performed to rule out anything cardiac, results were pending. On an unknown date in May-2025, she experienced mild low defenses and anemia. Information regarding corrective treatment included loperamide hydrochloride for diarrhea and not provided for rest of events. Outcome of the event fatigue and anemia were recovering, 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 related the events of fatigue, anemia, low defenses and lack of oxygen, while did not provide an opinion on relatedness with abemaciclib therapy.

Update 07-Jul-2025: Additional information was received from the initial reporting consumer via PSP on 26-jun-2025, initially this case was considered and case was upgraded to serious upon updating of non-serious event of fatigue from non-serious to serious via disability as seriousness criteria, two non-serious events of lack of oxygen and low defenses. Updated outcome and as reported causality for the the events of fatigue and anemia from not recovered to recovering, case and narrative accordingly with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	22-APR-2025	Red blood cell count decreased Positive 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