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		46 Years	Female	67.00 kg	04	APR	2025	

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

Stomach pain [Abdominal pain upper]
Patient started Verzenio once daily as stopped taking morning doses due to diarrhea, No AE [Inappropriate schedule of product administration]
diarrhea (more liquid)/ lot of diarrhea [Diarrhoea]
Headache [Headache]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) from a business partner, concerned a 46-year-old female patient of unknown ethnicity.

(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 {Lot # D802618; Exp.Dt. MAY-2027}

(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) 01-APR-2025 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) EXEMESTANO (EXEMESTANO) Tablet ; Unknown
#2) CALCIUM (CALCIUM) Tablet ; Unknown
#3) ESOMEPRAZOLE (ESOMEPRAZOLE) 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
MAR-2025 to Unknown	Medical Condition	Fasting (Fasting)
Unknown	Medical Condition	Dizziness (Dizziness)

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.
GT202504011059

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

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

DATE OF THIS REPORT
14-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

Mfr. Control Number: GT202504011059

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history included she fasted in Mar-2025, and dizziness at the end of the radiotherapy and fasting. Concomitant medications included esomeprazole for unspecified stomach disorder; calcium for unknown indications.

The patient received abemaciclib (Verzenio) coated tablets, 150 mg, every 12 hours, orally, for the treatment of breast cancer, beginning on 01-Apr-2025. As concomitant chemotherapy she received exemestane for breast cancer. On 04-Apr-2025, while on abemaciclib therapy, she had headache. On 07-Apr-2025, she experienced stomach pain and diarrhea at night; she went three times to defecate and it was normal but with stomach pain, on the fourth time she went to the bathroom it was diarrhea (more liquid). Both events continued in the morning of 08-Apr-2025. On 13-Apr-2025, she had lot of diarrhea, for this reason she stopped taking her morning dose of abemaciclib as she could not stand it (Inappropriate schedule of drug administration), and she had already consulted the treating physician about the side effects. Diarrhea lasted a week and she went to the bathroom up to ten times in one day. She ate in the street and that that could have made her sick. She was well, without any discomfort. She was taking lactobacillus medication for diarrhea and not provided for remaining events. Outcome of the events was not recovered however unknown for inappropriate schedule of drug administration. Abemaciclib therapy was ongoing.

The reporting consumer did not provide the causal relationship between the events and abemaciclib therapy.

Update 22-Apr-2025: Additional Information was received from the initial reporting consumer via PSP on 16-Apr-2025. Updated start date of abemaciclib therapy from 01-apr-2025 to 04-apr-2025 and action taken from no change to dose decreased. Added two non-serious events headache, Inappropriate schedule of drug administration, second dosage regimen slider and updated description as reported for event diarrhea. Updated concomitant medication lactobacillus to treatment medication for diarrhea. Narrative was updated with new information accordingly.

Update 13-May-2025: Additional Information was received from the initial reporting consumer via PSP on 06-May-2025. Updated start date and batch number along with dosage regimen of abemaciclib therapy. Added patient demographics weight and height, treatment medication enterogermin for diarrhea, Updated concomitant medication details of calcium, treatment details of lactobacillus, outcome and frequency of previously captured event diarrhea to recovered and narrative with new information accordingly.

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, daily; Unknown	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D785022; Exp.Dt. OCT-2026}; Regimen #3	150 mg, bid; Oral	Breast cancer (Breast cancer)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Radiotherapy (Radiotherapy);