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	COSTA RICA		PRIVACY		38 Years	Female	Unk	26	AUG	2024	

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

Stomach heaviness [Abdominal discomfort]
Patient administered 1 tablet of Verzenio all day, reason not provided; NO AE [Intentional product use issue]
Diarrhea/ Five bowel movements per day [Diarrhoea]

Case Description: This solicited case, reported by a consumer via patient support program (PSP) of business partner, with additional information from the initial reporter, concerned a 38-year-old female patient of unknown origin.

(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 # D689937; Exp.Dt. MAY-2026}

(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) 26-AUG-2024 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ARIMIDEX (ANASTROZOLE) Unknown ; Unknown
#2) GABAPENTIN (GABAPENTIN) Unknown ; Unknown
#3) CALCIUM (CALCIUM) Unknown ; Unknown
#4) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) 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
Unknown	Medical Condition	Neuropathic pain (Neuralgia)
Unknown	Procedure	Chemotherapy (Chemotherapy)

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.
CR202409001413

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

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

DATE OF THIS REPORT
04-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history included neuropathic pain and procedure included unspecified chemotherapy. Concomitant medication included calcium, vitamin D for an unknown indication and gabapentin for neuropathy.

The patient received abemaciclib (Verzenio) tablet of 150 mg, twice daily, via oral route for breast cancer, beginning on 26-Aug-2024. She also received concomitant medication of anastrozole for treatment of breast cancer. Same day after starting on abemaciclib therapy, she felt heavy in her stomach because of medication (abemaciclib). On an unknown date sometime in Sep-2024, she experienced a lot of diarrhea, five bowel movements per day. On 22-Sep-2024 and 29-Sep-2024, she intentionally took abemaciclib for once a day. When she took it for once a day, she does not have diarrhea. On an unknown date she again started taking abemaciclib twice a day. As a corrective treatment for diarrhea she took loperamide and lactobacillus reuteri, levoglutamide while corrective treatment for other events was not provided. On 01-May-2025, she experienced stomach heaviness when consuming certain specific food like sugary bread or ice cream. Outcome of the events was not recovered while unknown for intentional dose decreased. The status of abemaciclib therapy was dose reduced to once daily. Therapy was restarted with twice daily frequency and ongoing. This case was received per business alliance and therefore, follow-up will not be pursued. If additional information is received, the case will be updated accordingly.

The initial reporting consumer related the event stomach heaviness while did not provide the relatedness of other events with abemaciclib therapy.

Update 07-Oct-2024: Additional information was received from the initial reporting consumer via PSP on 30-Sep-2024. Added two dosage regimen of suspect product and two non-serious event of diarrhea and intentional dose decreased. Updated narrative with new information.

Update 03-Jun-2025: Additional information received on 27-May-2025 from the initial reporting consumer via a PSP. Information regarding stomach heaviness event was updated in narrative. No other changes were made to the case.

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; Oral	Breast cancer (Breast cancer)	Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet; Regimen #3	150 mg, bid; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown