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	COSTA RICA		PRIVACY		48 Years	Female	60.00 kg	14	JUL	2023	

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

Patient did not to go to the bathroom for 2 days was constipation [Constipation]
Stomach pain [Abdominal pain upper]
Diarrhea [Diarrhoea]
Lack of appetite (appetite absent) [Decreased appetite]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) in which they were enrolled, with additional information from the initial reporter, concerned a 48-year-old (at the time of initial report) female patient of an 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

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) Breast cancer (Breast cancer)

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

18. THERAPY DATES(from/to)
#1) 14-JUL-2023 / JUN-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
MAY-2022 to APR-2023	Medical Condition	Breast cancer (Breast cancer)

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.
CR202308007207

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

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

DATE OF THIS REPORT
12-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history included breast cancer from May-2022 to Apr-2023. Concomitant medications were not provided.

The patient received abemaciclib (Verzenio) tablets, 150 mg, twice daily (every 12 hours), orally, for the treatment of breast cancer, beginning on 14-Jul-2023. Concomitant chemotherapy, if any, was not provided. On 14-Jul-2023, the day she began abemaciclib therapy, she experienced diarrhea every 5 to 10 minutes that was continued, and she also had lack of appetite and stomach pain. On an unspecified date, the physician prescribed unspecified antidiarrheal medication, every 8 hours, via unknown route of administration for the treatment of diarrhea, that caused her to not to go to the bathroom for two days as she had constipation. She took antidiarrheal twice a day instead of every 8 hours but continued to have diarrheal stools. On an unspecified date in Jun-2025, abemaciclib therapy was discontinued due to unknown reasons. She had not recovered from the events. Information regarding treatment for the remaining events was not provided.

The reporting consumer did not provide an opinion of relatedness for the events with abemaciclib therapy, while related the event of constipation with unspecified antidiarrheal therapy.

Update 10-Aug-2025: Additional information was received on 04-Aug-2025 and 05-Aug-2025 from the initial reporter via a PSP. Added abemaciclib stop date, medical history of breast cancer, height and weight of patient. Updated case type from spontaneous to post-marketing; abemaciclib start date from 13-Jul-2023 to 14-Jul-2023 and narrative with new information.

Lilly Analysis Statement: 11-Aug-2025: The company considered the events of diarrhea and lack of appetite related to abemaciclib.