SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		71 Years	Female	Unk	19	MAR	2025

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

Diarrhea [Diarrhoea]
Tiredness [Fatigue]
Little hunger [Decreased appetite]
Diarrhea (second episode) [Diarrhoea]
Patient administered Verzenio 150 mg 1 per day, indicated by the treating physician [Off label use]

Case Description: This solicited case, reported by consumer via patient support program (PSP), with additional information from the initial reporter, concerned a 71-year-old female patient of an unknown origin.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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, daily

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

17. INDICATION(S) FOR USE
#1) Metastatic breast cancer in bone (Breast cancer metastatic)

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

18. THERAPY DATES(from/to)
#1) 19-MAR-2025 / Unknown

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)

#1) FAMARA (LETROZOLE) Unknown ; Unknown
#2) CRESTOR (ROSUVASTATIN CALCIUM) Unknown ; Unknown
#3) CARDIO ASPIRIN (ACETYLSALICYLIC ACID) Unknown ; Unknown
#4) AMLODIPINE (AMLODIPINE) Unknown ; Unknown
#5) PROCORALAN (IVABRADINE HYDROCHLORIDE) 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	Blood pressure increased (Blood pressure increased)
Unknown	Medical Condition	Blood cholesterol increased (Blood cholesterol increased)

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.
GT202504007259

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

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

DATE OF THIS REPORT
19-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history included blood pressure increased and blood cholesterol increased. Concomitant medication included rosuvastatin calcium for high cholesterol and acetylsalicylic acid, amlodipine and ivabradine hydrochloride, all for unknown indications.

The patient received abemaciclib (Verzenio) tablet, 150 mg daily (off label use), via oral route of administration, for the treatment of metastatic breast cancer in bone, beginning on 19-Mar-2025. She also received letrozole as a combination therapy, for an unknown indicating. On 30-Mar-2025, after starting abemaciclib therapy, she ate something that caused diarrhea. The diarrhea did not stop for three days and treated with loperamide and the next day the diarrhea was less. Since an unknown date, she felt tired and she was not very hungry because she does not have much room for food. On an unknown date, she was recovered from diarrhea. In May-2025, she would undergo tests to see how she reacts to the pill and according to the results, the doctor would tell her if she would have to go up the dose. The doctor would tell her whether to increase the dose to 1 tablet of 150 mg every 12 hours. On 05-April-2025, she experienced mild diarrhea. On 08-May-2025, per medical indication, abemaciclib dosage was started at 150 mg twice a day. Information regarding corrective treatment for remaining events was not provided. Outcome of diarrhea (first episode) was recovered, off label use was unknown and not recovered for remaining events. Status of abemaciclib therapy was continued.

The initial reporting consumer did not provide relatedness of events with abemaciclib therapy, also, diarrhea (second episode) was considered related to abemaciclib therapy (conflicting information)

Update 09-Apr-2025: This case was determined to be non-valid due to no valid identifiable adverse event reported (off label use).

Update 15-Apr-2025: This case was initially determined to be non-valid as there was no valid identifiable adverse event. Additional information received on 07-Apr-2025 from the initial reporting consumer via PSP, which contained valid adverse events. Added medical histories of high pressure and high cholesterols, concomitant medications of letrozole, rosuvastatin calcium, acetylsalicylic acid, amlodipine and ivabradine hydrochloride, one treatment medication of loperamide and three non-serious events of diarrhea, tiredness and decreased appetite. Updated narrative with new information.

Update 16-May-2025: Additional information received on 08-May-2025 from the initial reporter via a PSP. Added an abemaciclib dosage regime, and the dosages and route of administrations of: letrozole, rosuvastatin, acetylsalicylic acid, amlodipine and ivabradine were added. Updated narrative with new information.

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, bid; Oral	Metastatic breast cancer in bone (Breast cancer metastatic)	08-MAY-2025 / Ongoing; Unknown