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		68 Years	Female	Unk		JAN	2025

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

Gastritis [Gastritis]
Constipated [Constipation]
Abdominal gas [Flatulence]
Vomiting [Vomiting]
Diarrhoea [Diarrhoea]
Verzenio treatment was paused because it was not working / Verzenio treatment did not have the expected effect [Drug ineffective]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), through a business partner to report **(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

15. DAILY DOSE(S)
#1) 100 mg, bid

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

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

18. THERAPY DATES(from/to)
#1) 18-DEC-2024 / Unknown

19. THERAPY DURATION
#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☐ NA

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) LETROZOLE (LETROZOLE) Unknown ; Unknown
#2) GABAPENTIN (GABAPENTIN) Unknown ; Unknown
#3) CALCIUM (CALCIUM) Unknown ; Unknown
#4) IRON (IRON) Unknown ; Unknown
#5) PROBIOTICS NOS (PROBIOTICS NOS) Unknown ; Unknown
#6) SIMETHICONE (SIMETHICONE) 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	Neuropathy peripheral (Neuropathy peripheral)

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.
GT202502002199

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

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

DATE OF THIS REPORT
27-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

adverse events, with additional information from secondary reporting consumer, concerned a 68-years-old (at the time of initial report) female patient of an unknown origin.

Relevant medical history included neuropathy in hands and feet. Concomitant medications included calcium, iron, probiotics and simethicone all for unknown indication, and gabapentin for neuropathy.

The patient received abemaciclib (Verzenios) tablet, 100 mg, twice daily, orally for the treatment of breast cancer, beginning on 18-Dec-2024. She also received letrozole as concomitant chemotherapy. On an unknown date after taking the abemaciclib therapy on an empty stomach, it caused gastritis (upset stomach) and for this she had taken abemaciclib after eating something. On unknown date in mid-Jan-2025 she experienced diarrhoea and vomiting. Abemaciclib made her to vomit, especially at night. She also had abdominal gas. As a corrective treatment, her physician gave a medicine (unspecified) for vomiting, which she took for three days, and it cleared up the vomiting. She had up to ten diarrhoea episodes per day and on an unknown date in Jan-2025, the physician instructed her to take two loperamide tablets for one day. She had not taken loperamide again. She was constipated four days and on 30-Jan-2025 she had one bowel movement. On an unknown date, she experienced that abemaciclib therapy was not working and did not have the expected effect; abemaciclib therapy was discontinued due to the event and it was not expected to be restarted. At the end of Mar-2025, she had a biopsy performed (results, units and reference ranges were not provided) but according to the explanation provided by her oncologist the cancer had a mutation and it was no longer HER2 hormone positive but it was now triple negative. Information regarding corrective treatment for remaining events was not provided. Outcome for the events of gastritis, vomiting and diarrhoea was recovered, recovering for constipation and unknown for abdominal gas and lack of drug effect.

The initial reporting consumer related the event of vomit while did not provide the relatedness between the remaining events and abemaciclib therapy. The secondary reporting consumer did not provide an opinion on relatedness between the events and abemaciclib therapy.

Update 26-May-2025: Additional information was received from secondary reporting consumer via PSP on 20-May-2025. Added one laboratory data of biopsy and one non-serious event of lack of drug effect. Updated abemaciclib therapy status from no change to drug discontinued. Updated narrative accordingly.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAR-2025	Biopsy		
		No results, reference ranges or other information provided.		