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	08	MAY	2025	

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

Weight loss [Weight decreased]
Cramps [Abdominal pain]
Diarrhea [Diarrhoea]
Loss of appetite/not hungry [Decreased appetite]
Iron or salty water taste on the palate [Dysgeusia]
Anemia [Anaemia]
Patient did not administer a Verzenio dose, No AE [Product dose omission issue]

Case Description: This solicited case, reported by a consumer via a

(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

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)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 08-MAY-2025 / Ongoing	#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) ANASTROZOLE (ANASTROZOLE) Unknown ; Unknown
#2) GOSERELINE (GOSERELINE) Unknown ; Unknown
#3) IRON (IRON) Unknown ; Unknown
#4) ALFACALCIDOL (ALFACALCIDOL) Unknown ; Unknown
#5) IONIC CALCIUM (CALCIUM CHLORIDE, TRACE ELEMENTS 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

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.
CR202507010717

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

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

DATE OF THIS REPORT
18-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

Mfr. Control Number: CR202507010717

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient support program (PSP) from a business partner, concerned a 48-year-old female patient of unknown origin.

Medical history was not provided. Concomitant medications included iron, ionic calcium and alfacalcidol, all for unknown indications.

The patient received abemaciclib (Verzenio) tablets, 150 mg, orally, twice a day, for the treatment of breast cancer, starting on 08-May-2025. Concomitant chemotherapy included anastrazole and gosereline. On 08-May-2025, while on abemaciclib therapy, she experienced diarrhea and lack of appetite, she was eating very little. In May-2025, she experienced weight loss, she went from 65 kg in May-2025 to 60 kg in Jul-2025. On an unknown date, she experienced cramps followed by diarrhea, an iron or salty water taste on the palate and anemia. She took loperamide twice a day as corrective treatment for diarrhea. On 07-Jul-2025, she missed an abemaciclib dosage. Outcome of the events was not recovered. Abemaciclib therapy status was not changed.

The reporting consumer related the events to abemaciclib therapy.

Update 17-Jul-2025: Information received on 08-Jul-2025 and 11-Jul-2025 were processed at the same time.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAY-2025	Weight	65 kg	
2	JUL-2025	Weight	60 kg	