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	COSTA RICA		PRIVACY		49 Years	Female	53.00 kg	01	JUL	2023

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

Heartburn [Dyspepsia]
Abdominal pain/cramping in the pit of her stomach [Abdominal pain]
Nausea [Nausea]
feels pain in both legs of intensity 7/10 [Pain in extremity]
Feeling of fullness [Abdominal distension]
diarrhea [Diarrhoea]
Vomiting [Vomiting]
Hair loss [Alopecia]

Case Description: This solicited case, reported by a consumer via a **(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) 150 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) 15-JUN-2023 / Ongoing

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) ACETAMINOPHEN (ACETAMINOPHEN) 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	Breast cancer (Breast cancer)
	Onset: 05/2022 - End: 06/2024 - Ongoing: No	

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.
CR202307002384

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

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

DATE OF THIS REPORT
08-JUL-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

patient support program (PSP) of a business partner, with additional information from the initial reporter, concerned a 49-year-old female patient of unknown ethnicity.

Medical history included breast cancer. Concomitant medications included acetaminophen for an unknown indication.

The patient received abemaciclib (Verzenio), tablets, 150 mg, twice daily, orally, for the treatment of breast cancer, beginning on 15-Jun-2023. Concomitant chemotherapy was not provided. On 01-Jul-2023 while on abemaciclib therapy, she underwent a planned surgery to put breast implant where she underwent mastectomy to give her the benefit of her self-esteem. There were no complications, thus, she was at home and abemaciclib therapy was not discontinued. Also, on 01-Jul-2023, she experienced abdominal pain and cramping in the pit of her stomach. In addition, on 02-Jul-2023, she experienced nausea and heartburn. As corrective treatment for nausea she took famotidine, which was not prescribed by her physician. The events of abdominal pain, nausea and heartburn caused or prolonged her hospitalization. Later, since 01-Mar-2024, she felt pain in both legs of intensity 7/10. The leg pain occurred mainly after sitting and when she got up, as corrective treatment she was given unspecified analgesia provided by the pain clinic. On an unknown date, she also experienced diarrhea. She had several episodes of feeling nausea. On 10-JUL-2024, she experienced vomiting and she felt a ball in her stomach that until she vomited it went away (reportedly). Her children were going to take her to a gastroenterologist to see what it could be because she also was feeling of fullness, she did not take anything until the doctor saw her. On 20-Dec-2024, she experienced moderate to severe hair loss. On 21-Jun-2025, her abemaciclib therapy was discontinued due to competition of the therapy. Information regarding additional corrective treatments was not provided. She had not recovered from leg pain, nausea, vomiting, abdominal distension, hair loss and diarrhea, while outcome of remaining events was resolving. Abemaciclib therapy was ongoing. This case was received per business alliance and therefore, follow-up would not be pursued. If our partner receives any additional information, they will forward, and the case will be updated accordingly.

The reporting consumer did not provide a relatedness assessment between the events and abemaciclib therapy.

Update 06-Jul-2023: This case was determined to be non-valid as there was no identifiable adverse event only procedure.

Edit 07-Jul-2023: Upon review of initial information received on 03-Jul-2023, country was amended from Colombia to Costa Rica for the first reporter and for the patient information. No other changes performed.

Update 13-Jul-2023: Additional information was received on 10-Jul-2023 from the initial reporter via a PSP validating the case. Added three non-serious events of abdominal pain, nausea and heartburn and treatment drug. Updated abemaciclib start date. Narrative updated accordingly.

Update 08-Apr-2024: Additional information was received on 03-Apr-2024 from the initial reporter via a PSP. Both reports received on 03-Apr-2024 were processed at the same time. This case was upgraded to serious due to the addition of hospitalization criteria for abdominal pain, dyspepsia and nausea events. Added non-serious events of leg pain and diarrhea, and acetaminophen as concomitant medication. Updated case from spontaneous to post-marketing; abemaciclib start date; outcome of event abdominal pain, dyspepsia and nausea from not recovered to recovering; and narrative accordingly.

Update 23-Aug-2024: Additional information was received on 20-Aug-2024 from the initial reporter via a PSP. Added two non-serious events of abdominal distension and vomiting. Updated outcome of the event nausea to not resolved and narrative with new information.

Update 07-Feb-2025: Additional information was received on 03-Feb-2025 from the initial reporter via a PSP. Added one non-serious event of hair loss. Updated narrative with new information.

Update 07-Jul-2025: Additional information was received on 02-Jul-2025 from the initial reporter via a PSP. Added one medical history, patient’s weight, height, stop date of suspect drug. Updated narrative with new information.

Lilly Analysis Statement: 07-Jul-2025: The company considered the events nausea, diarrhea, vomiting, alopecia related to the abemaciclib.