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		65 Years	Female	73.00 kg		JUL	2024

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

suspected liver damage/hepatic disorder [Liver injury]
Abdominal pain/dolor abdominal [Abdominal pain]
Leg pain/ leg pain [Pain in extremity]
The patient was taking one table of Verzenio 150 mg one day [Off label use]
Joint pain [Arthralgia]
Pain as if it were the liver [Hepatic pain]
felt pain in the pit of her stomach (stomach ache) [Abdominal pain upper]
Waist pain/ Lower back pain [Back pain]
Swollen legs [Peripheral swelling]

(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 {Lot # D700887; Exp.Dt. MAY-2026}

(Continued on Additional Information Page)

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 female (Breast cancer female)

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

18. THERAPY DATES(from/to)
#1) 12-APR-2024 / 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) LETERO (LETROZOLE) Unknown ; Unknown
#2) METFORMIN (METFORMIN) Unknown ; 2023 / Unknown
#3) SITAGIL (SITAGLIPTIN PHOSPHATE) Unknown ; 2023 / Unknown
#4) FELODIPINE (FELODIPINE) Unknown ; Unknown
#5) RAMIPRIL (RAMIPRIL) 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
2023 to Unknown	Medical Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown	Medical Condition	Arterial hypertension (Hypertension)
	since before 2000	

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.
GT202408003217

24c. DATE RECEIVED BY MANUFACTURER
17-JUN-2025

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 8

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

No taste of food [Food aversion]
Diarrhea [Diarrhoea]
Tiredness increased [Fatigue]
Nausea [Nausea]
presents hunger but does not pass food/for 2 months has not eaten food beacuse the patient does not taste it (First episode) [Decreased appetite]
Headache [Headache]
Lack of appetite (second episode) [Decreased appetite]
Weakness, some days she doesn't get out of bed [Asthenia]
anemia [Anaemia]

Case Description: This solicited case reported by a consumer via Patient Support Program (PSP), concerned a 65-year female patient of an unknown origin.

Medical history included diabetes mellitus type two, arterial hypertension and fatigue. Concomitant medications included metformin, sitagliptin phosphate for diabetes mellitus type two, felodipine for blood pressure and ramipril for an unknown indication.

The patient received abemaciclib (Verzenio) tablet, 150 mg, twice daily, via oral route, for the treatment of breast cancer female, beginning 12-Apr-2024 (or 12-Jul-2024, discrepant start date reported). She also received letrozole for breast cancer, concomitantly. On an unknown date in Jul-2024, after starting abemaciclib therapy, she experienced diarrhea, there were days when she had between five and six liquid depositions, while other days she only had one or two depositions, but always with a soft or liquid consistency. The first time she presented with liquid diarrhea, with a liquid aspect, as a corrective treatment, she took metronidazole. Her tiredness increased, had pain in her legs and joints and felt pain in the pit of her stomach (stomachache) and a pain as if it were her liver (pain), for which she had a test (unspecified) to evaluate how her liver was doing. On an unknown date in Jul-2024, she developed abdominal pain/dolor abdominal, and her physician suspected it as liver damage. A hepatic ultrasound was supposed to be performed on unspecified date in Jul-2024, but the results were not provided. She did not receive any corrective treatment for the events of liver damage and abdominal pain. Her next appointment with her doctor would be in Nov-2024. As she had diarrhoea and nausea, and presented hunger but did not pass food due to which one month ago her physician indicated to suspend one-week abemaciclib, and then in the appointment of 14-Nov-2024, the physician indicated to take abemaciclib one day 1 tablet and the other day she would take 2 tablets. She had diarrhea for approximately four months since she had been taking it abemaciclib and the nausea started about two and a half months ago and for two months she had not eaten food, because she did not taste the food (first episode) (decreased appetite), and this caused her to feel nauseous. On 02-Dec-2024, she had headache and lack of appetite (second episode). On an unknown date, she has no taste of food. She was given several medications for the nausea and diarrhea; she had some sachets of cholestyramine and Loperamide for the diarrhea. She was also given protectis probiotics because she hardly ate. On an unknown date in Feb-2025, she had moderate weakness and some days she could not get out of bed. On an unknown date in Mar-2025, she was having moderate diarrhoea which was more than others. On an unknown date in May-2025, she was having severe anemia, lower back and leg pain, and swollen legs. On an unknown date in May-2025, her recent dose of abemaciclib therapy was discontinued. Information regarding further corrective treatment was unknown. Outcome of the events of appetite lost (first episode), nausea, off label use, stomachache, liver damage and abdominal pain was unknown; while for the remaining events, it was not resolved. Status of abemaciclib therapy was discontinued.

The initial consumer did not know the relatedness of the events of abdominal pain and liver damage, related the events of low back pain, leg pain and swelling of legs, did not relate the event of anemia while did not provide the relatedness of the remaining events with abemaciclib therapy. The secondary reporting consumer did not provide the relatedness of the events with abemaciclib therapy.

Update 26-Aug-2024: Additional information was received from the initial reporting consumer via PSP on 19-Aug-2024. Added weight of patient 73.48 kg and height 148 cm as her demographics; start dates of concomitant drugs of metformin and sitagliptin phosphate and two new non-serious events of abdominal pain and liver damage. Updated indication of suspect drug from breast cancer to breast cancer female and narrative with new information. Complete information present in all documents which were received on 19-Aug-2024, was processed together.

Update 19-Sep-2024: Additional information was received on 17-Sep-2024. No medically significant information was received, and no significant changes were made to the case.

Update 26-Nov-2024: Additional information was received from the secondary reporting consumer via PSP on 19-Nov-2024. Added an additional reporter consumer, an additional dosage regimen or abemaciclib 150 mg daily, two treatment medications for diarrhoea loperamide, cholestyramine and three non-serious evens of nausea, appetite lost and off label use. Updated the action taken form unknown to drug discontinued and the narrative with new information.

Update 12-Feb-2025: Additional information was received from the initial reporting consumer via PSP on 05-Feb-2025. Added three non-serious events of headache, food aversion and appetite lost (second episode). Updated narrative with relevant information.

Update 05-Mar-2025: Additional information was received from the initial reporting consumer via PSP on 05-Feb-2025. Updated therapy start date of abemaciclib from 12-Jul-2024 to 12-Apr-2024 (conflicting therapy start date reported), and narrative with relevant

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

information.

Update 10-Apr-2025: Additional information was received from the initial reporter via PSP on 06-May-2025. Added one non-serious event on asthenia and severety and frequency for the event of diarrhea. Updated corresponding fields and narrative with new information.

Update 21-May-2025: Additional information was received from the initial reporter via PSP on 12-May-2025 and 13-May-2025 were processed together. Added two non-serious event on anemia and diarrhea. Updated corresponding fields and narrative with new information.

Update 21-Jun-2025: Additional information was received from the initial reporter via PSP on 16-Jun-2025and 17-JUN-2025 were processed together. Added new dosage regimen of abemaciclib with batch details, non-serious events of low back pain and swelling of legs. Episode of leg pain subsumed under previously reported event of leg pain. Updated causality as reported for event anemia from related to not related, Updated causality as reported for event leg pain from not provided to related. Updated narrative with new information.

Update 26-Jun-2025: Additional information was received from the initial reporter via PSP on 17-Jun-2025 and 18-Jun-2025. Added therapy stop date for abemaciclib. Updated action taken of abemaciclib from ongoing to discontinued in narrative. Updated corresponding fields and narrative with new information.

Lilly Analysis Statement: 21-Jun-2025: The company considered the event of anemia related to the abemaciclib.

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, daily; Oral	Breast cancer female (Breast cancer female)	14-NOV-2024 / Unknown; Unknown
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D785022; Exp.Dt. OCT-2026}; Regimen #3	150 mg, daily; Oral	Breast cancer female (Breast cancer female)	Unknown / MAY-2025; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Fatigue (Fatigue);