CIOMS FORM

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		
		Day	Month	Year				Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		76 Years	Female	45.35 kg	11	FEB	2024

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

Respiratory discomfort [Respiratory disorder]
Cough [Cough]
White spot on lung [Lung disorder]
Shortness of breath [Dyspnoea]
Abdominal distension [Abdominal distension]
Stomach pain [Abdominal pain upper]
Stomach discomfort/ Upset discomfort [Abdominal discomfort]
Gas [Flatulence]
Stomach pain (2nd episode) [Abdominal pain upper]
Stool has a very bad odor [Abnormal faeces]

(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 # D645592; Exp.Dt. DEC-2025}

(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 (Breast cancer)

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

18. THERAPY DATES(from/to)
#1) 01-FEB-2024 / 05-JUN-2025

19. THERAPY DURATION
#1) 1 year 4 months 5 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) LANSOPRAZOLE (LANSOPRAZOLE) Unknown ; Unknown
#2) APROVEL (IRBESARTAN) Unknown, 150 mg; Unknown
#3) ESOMEPRAZOLE (ESOMEPRAZOLE) Unknown ; Unknown
#4) FULVESTRANT (FULVESTRANT) Injection ; FEB-2024 / Unknown
#5) ACETAMINOPHEN (ACETAMINOPHEN) Unknown, 500 mg; Unknown
#6) IBUPROFEN (IBUPROFEN) Unknown ; Unknown

(Continued on Additional Information Page)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
2014 to Ongoing	Medical Condition	Breast cancer (Breast cancer)
	a recurrence of breast cancer from 10 years ago	
2023 to Ongoing	Medical Condition	Cataracts (Cataract)

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.
GT202402009451

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Pain on the right side of her stomach, unsure if its related to her liver [Abdominal pain]
Pain on the right side of her stomach, unsure if its related to her liver [Liver disorder]
Patient had been cutting up the verzenio 100 mg for reaching a total daily dose of 300 mg, No AE [Wrong technique in product usage process]
Fall [Fall]
Discomfort [Discomfort]
Verzenio therapy was strong [Drug intolerance]
Neuropathy (such as pain in her fingers and toes, as if they were cramping) [Neuropathy peripheral]
Itchy [Pruritus]
Fatigue [Fatigue]
Diarrhea [Diarrhoea]
Diarrhea (second episode) [Diarrhoea]
Diarrhea (third episode) [Diarrhoea]
Rash on the body [Rash]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) and business partner, with additional information from the consumer, concerned a 76-years-old female patient of an unknown origin.

Medical history included breast cancer from 2014, high blood pressure since 2023, cataracts in her left eye since 2023, gastritis, and tonsil issues. Concomitant medications included lansoprazole (on an empty stomach), irbesartan, esomeprazole, acetaminophen, and ibuprofen, all for unknown indications and lactobacillus reuteri as probiotic therapy

The patient received abemaciclib (Verzenio) tablets, 150 mg twice daily via oral route for the treatment of breast cancer, beginning on 01-Feb-2024. As concomitant chemotherapy, she received fulvestrant. On 11-Feb-2024, 11 days after being on abemaciclib therapy and after consuming chocolate, she started experiencing abdominal distension, which bothered her. She was advised to avoid consuming dairy, fats, and foods that could cause gas. On 21-Feb-2024, she experienced stomach pain and had two bowel movements resembling diarrhea, but not exactly watery, somewhat pasty consistency. She took bacillus clausii as a corrective treatment, which helped. On 22-Feb-2024, she experienced stomach pain due to eating food outside her home. She went to the bathroom, but the consistency of the bowel movements was normal. On 23-Feb-2024, 23 days after starting treatment with abemaciclib therapy, she experienced stomach discomfort, feeling of pain, gas, and abdominal distension. Reportedly, she had occasional stomach pain, attributing it to having consumed a bit of chocolate on one occasion, and she believed that it caused the discomfort. On 26-Feb-2024, 26 days after abemaciclib therapy, she again had diarrhea and decided to consult. She followed dietary recommendations given by the nutritionist but had not started taking loperamide, as it was advised that the symptoms were common side effects. On an unknown date in Feb-2024, she experienced severe respiratory discomfort. On 04-Mar-2024, she experienced diarrhea (third episode) and stomach pain (second episode). On 08-Mar-2024, she woke up at 4:00 am with a strong pain on the right side of her stomach and she was not sure if it was related to her liver, she then used the bathroom, and the pain decreased a bit and gradually went away. She continued to had stomach discomfort and sometimes she had stomach pain and whatever she eats, it caused diarrhea. Sometimes, she did not had discomfit in stomach after eating, but had diarrhea after an hour or two hours. She received protectis for upset stomach and felt improvement and took saline solution for diarrhea. On the same date, she recovered from the pain on the right side of her stomach. On an unknown date, she experienced that her stool had a very bad odor. From an unknown date, she began taking abemaciclib at 100 mg (one and a half pills in the morning and one and a half pills in the evening) for a total daily dose of 300 mg. On 16-Sep-2024, she fell while on her way to a consultation, that she did not get hurt apparently because she managed to put her hands in. Reportedly, she had not been able to have surgery for her cataract due to abemaciclib therapy, but she planned to follow up with ophthalmology in a month. On an unknown date her discomfort became stronger when she started using the abemaciclib therapy because she mentions that the abemaciclib therapy was strong and for that reason it causes such discomfort, as a corrective treatment she had taken unspecified medication that was given to her at the Iggs, it helped her to improve a lot. On an unknown date about two months ago she has been experiencing neuropathy discomfort such as pain in her fingers and toes, as if they were cramping, she consulted the doctor about these symptoms and he indicated that it was neuropathy. On 07-Nov-2024, at her appointment in oncology to pick up her abemaciclib medication, but she no longer received the medication, she was currently waiting for the abemaciclib but continues using abemaciclib, she consulted the Oncologist about her operation that was scheduled on 19-Nov-2024 in her left eye due to a cataract, since she had previously consulted him but since she was starting with the abemaciclib treatment, they told the patient to wait, But since the patient had already been told that she could have surgery on her left eye, she scheduled the operation for 19-Nov-2024. Oncologist recommended that the patient stop using abemaciclib 5 days before the operation and 5 days after. On 10-Nov-2024, he had rash on his body and felt very itchy for which he took ebastine as corrective treatment. She was on a dose of 150 mg every 12 hours at the time the event occurred. The medication was not discontinued. She reported severe itching and mentioned that more than 30% of her body surface area was affected. There were no target lesions, no mucosal involvement, and no signs of Nikolskys syndrome. On an unknown date in Mar-2025, she experienced moderate cough, fatigue, shortness of breath and lung x-ray showed white spot-on lung. On 05-Jun-2025, she discontinued abemaciclib due to respiratory discomfort, cough, and white spot-on lung. As a corrective treatment she took unspecified digestive enzymes for upset her stomach, pregabalin for neuropathy. No treatment required for events fatigue and shortness of breath. Information regarding corrective treatment for the remaining events was not provided. The outcome of the events of abdominal distension, gas, diarrhea (third episode), stomach pain (second episode), stools with a bad odor, rash generalised, itchy, cough, fatigue, shortness of breath, and lung disorder was not resolved, the outcome unknown for tablet split incorrectly, stomach discomfort, liver disorder, diarrhea (second episode), neuropathy peripheral and drug intolerance. She was recovering from the fall, discomfort,

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

respiratory disorder and had recovered from the remaining events. It was unknown whether tirzepatide treatment would be restarted.

The initial reporting consumer related the events itchy, discomfort, respiratory disorder, cough, fatigue, shortness of breath, and lung disorder and did not provide relatedness assessment of the remaining events with abemaciclib therapy.

Update 01-Mar-2024: Additional information was received from an initial reporting consumer on 23-Feb-2024. Added three non-serious events stomach pain, diarrhea, tablet split incorrectly, treatment drug bacillus clausii, concomitants irbesartan, esomeprazole and fulvestrant. Updated patient initials and narrative with new information.

Update 06-Mar-2024: Additional information was received from an initial reporting consumer via business partner and PSP on 27-Feb-2024. Added three non-serious events of gas, stomach discomfort, and diarrhea (second episode), frequency of the event stomach pain and one medical history. Updated the corresponding field and narrative accordingly.

Update 22-Mar-2024: Additional information was received from the reporting consumer via business partner on 14-Mar-2024. Added five non serious events of diarrhea (third episode), stomach pain (second episode), abnormal faeces, abdominal pain, and liver disorder. Added medical history of gastritis, tonsil issues and blood pressure increased, added batch number for abemaciclib therapy. Updated abemaciclib therapy start date. Acetaminophen and ibuprofen were added as concomitant therapy. Narrative updated with new information accordingly.

Update 28-Mar-2024: Information was received from the reporting consumer via business partner on 22-Mar-2024. No new information was received.

Update 04-Apr-2024: Information was received from reporting consumer via business partner on 01-Apr-2024. No new information was received.

Update 22-Sep-2024: Additional information was received from initial reporting consumer via business partner and PSP on 16-Sep-2024. Added one medical history of cataracts in left eye, one dosage regimen of 150mg (100 mg tablet; One and a half tablets in the morning and one and a half tablets at night) with unknown batch detail and one non-serious event of fall. The narrative was updated with new information.

Update 19-Nov-2024: Additional information was received from initial reporting consumer via business partner and PSP on 12-Nov-2024 added one concomitant medcition as lactobacillus reuteri, one treatment medication of pregabalin, three non-serious events of discomfort and drug intolerance, neuropathy peripheral. Updated narrative with new information.

Update 03-Mar-2025: Additional information was received from initial reporting consumer via business partner and PSP on 24-Feb-2025. Added two new non-serious events of rash generalised, and itchy. Added one new treatment medication ebastine. Narrative was updated with new information accordingly.

Update 25-Mar-2025: Additional information was received from initial reporting consumer via business partner and PSP on 14-Mar-2025. Added patient height and weight. Updated severity of the event itchy to severe, and causality to related. Narrative was updated with new information.

Update 19-Jun-2025: Additional information was received from initial reporting consumer via business partner and PSP on 16-Jun-2025. Added one non-serious event of respiratory disorder. Updated action taken with abemaciclib from no change to drug discontinued. Narrative was updated with new information.

Update 25-Jun-2025: Additional information was received from initial reporting consumer via business partner and PSP on 19-Jun-2025. Added four non-serious events of cough, fatigue, shortness of breath, and lung disorder. Narrative was updated with new information.

Lilly Analysis Statement: 19-Jun-2025: The company considered the events diarrhoea, rash related to the abemaciclib therapy and event discomfort unrelated to the abemaciclib therapy.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Chest X-ray White spot on lung		

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

ADDITIONAL 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 (100mg, one and half tab in morning and evening); Oral	Breast cancer (Breast cancer)	Unknown; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#7) BIOGAIA PROTECTIS (LACTOBACILLUS REUTERI) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Gastritis (Gastritis);
Unknown	Medical Condition	Tonsillar disorder (Tonsillar disorder);
2023 to Unknown	Medical Condition	Blood pressure increased (Blood pressure increased);