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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	GUATEMALA		PRIVACY		65 Years	Female	63.30 kg	24	APR	2025	

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

Cough [Cough]
vocal cord damage [Vocal cord disorder]
Taking 1 tablet of 150 mg every 24 hours [Off label use]
Abdominal pain [Abdominal pain]
Increased blood pressure [Blood pressure increased]
Skin rash [Rash]
Diarrhea 2 or 3 times a day [Diarrhoea]
Headache on occasion [Headache]
Physical exhaustion [Fatigue]
Loss of appetite [Decreased appetite]

(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) Film-coated tablet
#2) PANTECTA (PANTOPRAZOLE SODIUM SESQUIHYDRATE)

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, daily	#1) Oral
#2) 40 mg, daily	#2) Oral

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) Gastric protector (Gastrointestinal disorder prophylaxis)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 24-APR-2025 / Unknown	#1) Unknown
#2) 2020 / Ongoing	#2) Unknown

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) PROCORALAN (IVABRADINE HYDROCHLORIDE) Unknown ; Unknown
#3) EUTIROX (LEVOTHYROXINE SODIUM) Unknown ; Unknown
#4) SELVIGON (PIPAZETATE HYDROCHLORIDE) Unknown ; Unknown
#5) PREGABALIN (PREGABALIN) Unknown ; Unknown
#6) BUDENA (BUDESONIDE) 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
Unknown to Ongoing	Medical Condition	Hypothyroidism (Hypothyroidism)
Unknown to Ongoing	Medical Condition	Arrhythmia (Arrhythmia)

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.
GT202504024842

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

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

DATE OF THIS REPORT
02-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Nausea [Nausea]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) from a business partner, with additional information from another consumer via PSP of a business partner, concerned a 65-year-old female patient of unknown ethnicity.

Medical history included hypothyroidism, arrhythmia, insomnia, lung metastasis, diverticulosis and had unspecified chemotherapy treatment every three weeks and after each session the patient was convalescent. Concomitant medications included coderpina, respliquen, subimex (as reported), ivabradine hydrochloride, levothyroxine sodium, pipazetate hydrochloride, pregabalin, budesonide, ipratropium bromide, clonixin lysinate/pargeverine hydrochloride; all for unknown indications.

The patient received pantoprazole sodium sesquihydrate (Pantecta), gastro-resistant tablets, 40 mg, daily, orally, as gastric protector beginning in 2020. She also received abemaciclib (Verzenio) film coated tablets, 150 mg, daily (off-label dosing frequency), via oral, for the treatment of breast cancer, beginning on 24-Apr-2025. As concomitant chemotherapy she received letrozole for breast cancer. Reportedly she was taking one tablet of 150 mg every 24 hours. She will be taking it this way for two weeks (time unspecified) and then she will be evaluated to take 1 tablet of 150 mg every 12 hours. On 04-May-2025, while on abemaciclib and pantoprazole sodium sesquihydrate therapies, she experienced moderate cough with vocal cord damage, headache on occasion and mild physical exhaustion. Unspecified corrective treatment was received for cough with vocal cord damage. On 05-May-2025, she experienced diarrhea two or three times a day and skin rash. As corrective treatment, she was taking sodium chloride for diarrhea. On 06-May-2025, her diarrhoea increased to 6 to 8 per day (intensity moderate) by taking 4 tablets over the course improved between 2 to 4 diarrhoeas. Reportedly, she still taking 150mg at every 24hours due to nausea, abdominal pain, headache, cough, decay, skin rashes, on two unknown occasions the her blood pressure increased (no values, units and reference ranges were provided), on two unknown occasions she had a fever of 38.5 (degrees) and also due to the loss of appetite that she began to present on 27-May-2025, for which reason the dose of abemaciclib has not yet been increased to two per day. As a corrective treatment she received megestrol acetate for treatment of loss of appetite, while corrective treatment for remaining events was not provided. Outcome of events was not recovered. Abemaciclib and pantoprazole sodium sesquihydrate therapies were ongoing. Follow-up could not be attempted since the reporter did not agree to be contacted and healthcare professional contact details were not provided.

The first reporting consumer did not provide an opinion of relatedness between the events and abemaciclib therapy either with pantoprazole sodium sesquihydrate therapy. The second reporting consumer did not relate event of vocal cord damage to abemaciclib, did not provide relatedness assessment between off label dosing frequency and abemaciclib, while related the remaining events to abemaciclib therapy and did not provide an opinion of relatedness between the events and pantoprazole sodium sesquihydrate therapy.

Update 06-May-2025: This case was determined to be non valid due to no identifiable adverse event.

Update 07-May-2025: Additional information was received on 25-Apr-2025. Updated report type from spontaneous to post-marketing study. The case remained as non-valid due to no identifiable adverse event (off label use only).

Update 19-May-2025: Additional information was received on 09-May-2025 from the second reporter consumer via PSP of a business partner. This case was validated due to the addition of the following non-serious events: cough, vocal cord disorder, diarrhea, headache, fatigue and rash. Added second dosage regimen of abemaciclib and sodium chloride treatment. Updated outcome of off-label use to recovered. Upon review of previous information, the description to be coded of off-label use was updated to off label dosing frequency and start date was added; deleted concomitant therapies of codeine, amoxicillin trihydrate, and buprenorphine hydrochloride/naloxone hydrochloride as reported trade name was not available in world drug dictionary. Narrative was updated accordingly with new information.

Update 26-May-2025: Additional information received on 22-May-2025 via a PSP. Added the intensity as moderate for the event diarrhoea and updated loperamide from concomitant medication to treatment drug for diarrhea. Updated the narrative with new information.

Update 31-May-2025: Additional information was received from consumer via PSP on 28-May-2025. Added patient demographics (height and weight), two laboratory data of blood pressure and body temperature; one suspect dose regimen with new batch number; one treatment medication of megestrol acetate; five non serious events of increased blood pressure, fever, loss of appetite, nausea and abdominal pain. Updated As Reported Causality for event of cough from not related (NO) to related (YES); updated outcome for event of headache from Recovering to not recovered; updated corresponding fields and narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement		
		Increased (no values, units and reference ranges were provided)		

Mfr. Control Number: GT202504024842

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
2		Body temperature high	38.5 °C	

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) Film-coated tablet; Regimen #2	150 mg, bid; Oral	Breast cancer (Breast cancer)	Ongoing; Unknown
#1) Abemaciclib (Abemaciclib) Film-coated tablet {Lot # D802618; Exp.Dt. MAY-2027}; Regimen #3	150 mg, daily; Oral	Breast cancer (Breast cancer)	24-APR-2025 / Unknown; Unknown
#2) PANTECTA (PANTOPRAZOLE SODIUM SESQUIHYDRATE) Gastro-resistant tablet, 40 mg; Regimen #1	40 mg, daily; Oral	Gastric protector (Gastrointestinal disorder prophylaxis)	2020 / Ongoing; Unknown

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

#7) ATROVENT (IPRATROPIUM BROMIDE) Unknown ; Unknown

#8) SERTAL COMPUESTO [CLONIXIN LYSINATE;PARGEVERI (CLONIXIN LYSINATE, PARGEVERINE HYDROCHLORIDE) Unknown ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Insomnia (Insomnia);
Unknown to Ongoing	Medical Condition	Lung metastases (Metastases to lung);
Unknown to Ongoing	Medical Condition	Diverticulosis (Diverticulum intestinal); indicates that 5 days ago she finished antibiotics for diverticulitis
Unknown to Ongoing	Medical Condition	Convalescent (Convalescent);
Unknown to Ongoing	Procedure	Chemotherapy (Chemotherapy); chemotherapy treatment every three weeks