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		82 Years	Female	Unk		Unk	

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

Paleness [Pallor]
Weight loss (2 pounds) [Weight decreased]
liver enzymes are high [Hepatic enzyme increased]
High bilirrubin [Blood bilirubin increased]
Patient administered Verzenio at a frequency of once a day, No AE [Inappropriate schedule of product administration]
platelets are very low [Platelet count decreased]
Digestion problems [Dyspepsia]
Poor appetite (Lack of appetite) [Decreased appetite]

(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

(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, bid	#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)	19. THERAPY DURATION
#1) 03-JAN-2024 / Unknown	#1) 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) COLVER (CARVEDILOL) Unknown, 2.5 mg; Unknown
#3) GALVUS MET (METFORMIN HYDROCHLORIDE, VILDAGLIPTIN)
#4) ELIQUIS (APIXABAN) Unknown, 5 mg; Unknown
#5) QUETIDIN (QUETIAPINE FUMARATE) Unknown ; Unknown
#6) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) 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	Hypertension (Hypertension)

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.
GT202401014329

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

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

DATE OF THIS REPORT
21-MAY-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.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This solicited case, reported by consumers via a business partner and patient support program (PSP), concerned an 82-year-old female patient of an unknown origin.

Medical history included high blood pressure/hypertension. Concomitant medications included carvedilol; metformin hydrochloride, vildagliptin; apixaban; quetiapine fumarate; ascorbic acid; silybum marianum; probiotics NOS; fish oil; magnesium; zinc; colecalciferol, vitamin K NOS; sulforaphane; calcium, colecalciferol, magnesium, zinc; lauricidin (as reported); mushrooms; and ascorbic acid, biotin, calcium pantothenate, colecalciferol, cyanocobalamin, folic acid, nicotinamide, pyridoxine hydrochloride, riboflavin, thiamine hydrochloride, tocopheryl acetate, irbesartan and collagen with protein (as reported); all used for treatment of unknown indications.

The patient received abemaciclib (Verzenio) tablet, 150 mg twice a day, orally, for the treatment of breast cancer, beginning on 03-Jan-2024 along with letrozole for treatment of an unknown indication, concomitantly. On an unknown date, while on abemaciclib therapy, she had poor appetite, paleness and lost 2 pounds weight (reference range was not provided). She was on low-carbohydrate diet and was instructed by the oncologist to resume it in order not to lose weight. On an unknown date, while on abemaciclib therapy, after a blood report test it was identified that she had very low platelets i.e. 77,000 (unit and reference range not provided) which are lower than those she had a month ago (grade 2), had digestion problems and liver enzymes were high they went from 48 to 56 (unit and reference range not provided). Furthermore, the antigen decreased from 62 to 52. Since an unknown date in Jul-2024, she was taking abemaciclib therapy at a dose of 150 mg daily and had better appetite and had not had problem with digestion. She had severe high bilirubin (unit and reference range not provided) and was affecting the liver and she started using only one 150mg tablet per day 5 months ago (inappropriate schedule of drug administration). Due to the event of high bilirubin, her abemaciclib therapy was suspended approximately since Mar-2025 (one-two weeks ago as of 08-Apr-2025). Information regarding corrective treatment was not provided. Outcome of the event digestion impaired and appetite lost was resolving, not provided of the events blood bilirubin increased and inappropriate schedule of drug administration and not resolved for rest of the events. It was unknown if abemaciclib therapy would be resumed or not.

The initial reporting consumers considered high bilirubin as related and did not provide the relatedness assessment of the remaining events with abemaciclib therapy.

Update 02-Sep-2024: Additional information was received from secondary consumer via a business partner and patient support program (PSP) on 26-Aug-2024. Added medical history of high blood pressure/hypertension, two laboratory tests for the event of elevated liver enzymes, platelet count low, three non-serious events of elevated liver enzymes, platelet count low, digestion impaired and one new dosage regimen of abemaciclib therapy. Updated outcome of event appetite lost was recovering, action taken of suspect drug from no change to dose decreased and onset date of treatment from 18-Jan-2024 to 03-Jan-2024 and the narrative with new information.

Update 12-Apr-2025: Additional information was received from consumer via a business partner and patient support program (PSP) on 08-Apr-2025. Added one lab test of blood bilirubin increased, and two non-serious new event of blood bilirubin increased, and inappropriate schedule of drug administration. Updated action taken of suspect drug from dose decreased to drug discontinued, and narrative accordingly with new information.

Update 05-May-2025: Information was received from consumer via a business partner and patient support program (PSP) on 30-Apr-2025. No new medically significant information was received and hence no changes were made to the case.

Update 20-May-2025: Information was received from consumer via a business partner and PSP on 13-Apr-2025. Added severity of high bilirubin as severe and causality as yes from no. Updated narrative accordingly with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood bilirubin Positive High (unit and reference range not provided).		
2		Hepatic enzyme Positive 48 high values, units and reference ranges were not provided.		
3		Hepatic enzyme Positive 56		

Mfr. Control Number: GT202401014329

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		high values, units and reference ranges were not provided.		
4		Platelet count Negative 77,000 low (unit and reference range not provided).		
5		Weight Positive patient lost 2 kg reference ranges were not provided.		

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 (Breast cancer)	JUL-2024 / Unknown; Unknown

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

#3) GALVUS MET (METFORMIN HYDROCHLORIDE, VILDAGLIPTIN) Unknown, 250 mg; Unknown

#7) MILK THISTLE [SILYBUM MARIANUM] (MILK THISTLE [SILYBUM MARIANUM]) Unknown ; Unknown

#8) PROBIOTICS NOS (PROBIOTICS NOS) Unknown ; Unknown

#9) OMEGA 3 [FISH OIL] (FISH OIL) Unknown ; Unknown

#10) MAGNESIUM (MAGNESIUM) Unknown ; Unknown

#11) ZINC (ZINC) Unknown ; Unknown

#12) VITAMIN D+K (COLECALCIFEROL, VITAMIN K NOS) Unknown ; Unknown

#13) PERFECTIL [ASCORBIC ACID;BIOTIN;CALCIUM PANTO (ASCORBIC ACID, BIOTIN, CALCIUM PANTOTHENATE, COLECALCIFEROL, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN, THIAMINE HYDROCHLORIDE, TOCOPHERYL ACETATE) Unknown ; Unknown

#14) SULFORAPHANE (SULFORAPHANE) Unknown ; Unknown

#15) OSTEOCARE [CALCIUM;COLECALCIFEROL;MAGNESIUM;Z (CALCIUM, COLECALCIFEROL, MAGNESIUM, ZINC) Unknown ; Unknown

#16) APROVEL (IRBESARTAN) Unknown ; Unknown