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		60 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)

Other Serious Criteria: Med Sig
Kidney failure [Renal failure]
Had a bacteria, that was getting into her blood [Haematological infection]
Anemia [Anaemia]
Difficulty with vision which hurt and she cannot read [Visual impairment]
Difficulty with vision which hurt and she cannot read [Eye pain]

Case Description: This solicited case, reported by a consumer via a Patient Support Program (PSP) through a business partner, concerned a 60-year-old (at the time of initial report) female patient of an unknown

(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) 28-AUG-2024 / 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) SALBUTAMOL (SALBUTAMOL) Unknown ; Unknown
#2) IRBESARTAN (IRBESARTAN) Unknown, 150 mg; Unknown
#3) LORATADINE (LORATADINE) 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 to Ongoing	Medical Condition	Anemia (Anaemia)
Unknown to Ongoing	Medical Condition	Blood pressure high (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.
CR202503020914

24c. DATE RECEIVED BY MANUFACTURER
21-MAR-2025

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

DATE OF THIS REPORT
27-MAR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

origin.

Medical history included breast cancer, anemia, high blood pressure, asthma, allergies and diabetes. Concomitant medications included salbutamol spray and an unspecified spray for the treatment of asthma, irbesartan for the treatment of high blood pressure, loratadine for the treatment of allergies and unspecified white insulin injection for the treatment of diabetes.

The patient received abemaciclib (Verzenio) tablet at 150 mg twice daily dose via orally for the treatment of breast cancer beginning on 28-Aug-2024. On an unknown date, while on abemaciclib therapy, she was hospitalized as she was diagnosed with kidney failure. She had a bacteria that was getting into her blood and also because of advanced anemia for which she received three bags of blood as a corrective treatment. The events of anaemia and haematological infection were considered as serious by the company due to medically significant reasons. She had difficulty with her vision, it hurt, became very dirty and she could not read. She thought that it might be the same kidney infection that was spreading everywhere in her body. Her asthma (medical history) was subsided slightly, but as of 21-Mar-2025, as her immune system was low, asthma had returned. She used two sprays (one salbutamol and other unspecified). Information regarding the hospitalization details and corrective treatment for the remaining events was not provided. Outcome of the events was not resolved. Therapy status of abemaciclib therapy was ongoing.

The initial reporting did not provide any assessment on relatedness for the events with abemaciclib therapy.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Asthma (Asthma);
Unknown to Ongoing	Medical Condition	Allergy (Hypersensitivity);
Unknown to Ongoing	Medical Condition	Diabetes (Diabetes mellitus);
Unknown to Ongoing	Medical Condition	Breast cancer (Breast cancer);