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	COSTA RICA		PRIVACY		Unk	Female	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Vomiting [Vomiting]	OSIMERTINIB	No	No	Related	Related
Diarrhea [Diarrhoea]	OSIMERTINIB	No	Yes	Related	Related
Headache [Headache]	OSIMERTINIB	No	No	Related	Related
Skin allergy [Hypersensitivity]	OSIMERTINIB	No	No	Related	Related

(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
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) OSIMERTINIB (OSIMERTINIB) Tablet

15. DAILY DOSE(S)
#1) 80 milligram, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) LUNG CANCER (Lung neoplasm malignant)

18. THERAPY DATES(from/to)
#1) 30-MAY-2025 / 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)

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	Indication	Lung cancer (Lung cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: CR-ASTRAZENECA-202506CAM013864CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00893218A

24b. MFR CONTROL NO.
202506CAM013864CR

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

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

DATE OF THIS REPORT
20-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1977.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Osimertinib (osimertinib) 80 milligram qd, Oral use, on 30-MAY-2025 for lung cancer.

On an unknown date, the patient experienced vomiting (preferred term: Vomiting), headache (preferred term: Headache), diarrhea (preferred term: Diarrhoea) and skin allergy (preferred term: Hypersensitivity).

The dose of Osimertinib (osimertinib) was not changed.

At the time of reporting, the event diarrhea, headache, skin allergy and vomiting was improving.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event (s): diarrhea, headache, skin allergy and vomiting.
The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): diarrhea, headache, skin allergy and vomiting.