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		66 Years	Female	Unk	16	NOV	2023

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

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
DIARRHEA [Diarrhoea]	OSIMERTINIB	Yes	Yes	Related	Related
LESS HUNGRY [Decreased appetite]	OSIMERTINIB	No	No	Related	Related
UVEITIS IN THE EYES [Uveitis]	OSIMERTINIB	Yes	No	Related	Related
Injury to the inside of the nose [Nasal injury]	OSIMERTINIB	No	No	Related	Related
Mouth lesions [Stomatitis]	OSIMERTINIB	No	Yes	Related	Related
Dry nose [Nasal dryness]	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) 16-NOV-2023 / 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 neoplasm malignant)

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-2024A055423
Study ID: PSP-23269
Case References: CR-AstraZeneca-2024A055423

24b. MFR CONTROL NO.
2024A055423

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

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

DATE OF THIS REPORT
02-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Brote en la espalda [Rash]	OSIMERTINIB	No	Yes	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning about a female elderly patient born in 1957 (age 66 years).

No medical history and concomitant products were reported.

On 16-NOV-2023, The patient started treatment with Osimertinib (osimertinib) 80 milligram qd, Oral use, for lung cancer.

On 16-NOV-23, the patient experienced less hungry (preferred term: Decreased appetite), diarrhea (preferred term: Diarrhoea) and uveitis in the eyes (preferred term: Uveitis). On 27-FEB-24, the patient experienced injury to the inside of the nose (preferred term: Nasal injury). On an unknown date, the patient experienced mouth lesions (preferred term: Stomatitis) and dry nose (preferred term: Nasal dryness).

The dose of Osimertinib (osimertinib) was not changed.

The outcome of the event(s) of diarrhea, dry nose, less hungry, mouth lesions and uveitis in the eyes was unknown. At the time of reporting, the event injury to the inside of the nose was ongoing.

The following event(s) were considered serious due to medically significant:diarrhea and uveitis in the eyes.

The following events were considered non-serious:dry nose, injury to the inside of the nose, less hungry and mouth lesions.

The reporter considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event (s): diarrhea, dry nose, injury to the inside of the nose, less hungry, mouth lesions and uveitis in the eyes.
The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): diarrhea, dry nose, injury to the inside of the nose, less hungry, mouth lesions and uveitis in the eyes.

The events mouth lesions (preferred term: Stomatitis) and dry nose (preferred term: Nasal dryness) have been identified by the company physician from the source documents and added as adverse events.

Summary of the follow up information received by AstraZeneca on 26-Mar-2025 from a consumer via Patient Support Program: New events injury to the inside of the nose (preferred term: Nasal injury), mouth lesions (preferred term: Stomatitis) and dry nose (preferred term: Nasal dryness) were added. Narrative updated.

Company Clinical Comment: Uveitis is not listed in the company core data sheet of osimertinib. Underlying lung cancer could be confounding. Due to limited information on circumstances leading to event, recent statis of underlying malignancy, outcome of events, clinical course, treatment provided, risk factors, relevant medical history, concurrent conditions, concomitant medications, detailed diagnostic and etiologic workup, the evaluation did not find the evidence to exclude a causal relationship between the event and suspect drug.