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		Unk	Female	Unk			2024

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
Body pain [Pain]	OSIMERTINIB	No	No	Related	Related
Back pain [Back pain]	OSIMERTINIB	No	No	Related	Related
Diarrhea [Diarrhoea]	OSIMERTINIB	No	Yes	Related	Related
Lack of appetite [Decreased appetite]	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) 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)

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 #: GT-ASTRAZENECA-202505CAM009294GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00868753A

24b. MFR CONTROL NO.
202505CAM009294GT

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

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

DATE OF THIS REPORT
16-MAY-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 1946.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Osimertinib (osimertinib) 80 milligram qd, Oral use, during 2024 for lung cancer.

During 15-JUN-24, the patient experienced body pain (preferred term: Pain), lack of appetite (preferred term: Decreased appetite), diarrhea (preferred term: Diarrhoea) and back pain (preferred term: Back pain).

The dose of Osimertinib (osimertinib) was not changed.

The outcome of the event(s) of back pain, body pain, diarrhea and lack of appetite was unknown.

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): back pain, body pain, diarrhea and lack of appetite.

The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): back pain, body pain, diarrhea and lack of appetite.