CIOMS FORM

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	DOMINICAN REPUBLIC		PRIVACY		Unk	Male	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
THE PATIENT DEVELOPED PNEUMONITIS DURING TREATMENT WITH TAGRISSO [Pneumonitis]	TAGRISSO	Yes	Yes	Related	Not 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) TAGRISSO (OSIMERTINIB) Tablet {Lot # UNK}

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

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

17. INDICATION(S) FOR USE
#1) Non-small cell lung cancer (Non-small cell lung cancer)

18. THERAPY DATES(from/to)
#1) Unknown

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	Non-small cell lung cancer (Non-small cell 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 #: DO-ASTRAZENECA-202508CAM006101DO
Study ID: N/A
Case References: DO-AstraZeneca-CH-00928068A

24b. MFR CONTROL NO.
202508CAM006101DO

24c. DATE RECEIVED BY MANUFACTURER
09-AUG-2025

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

DATE OF THIS REPORT
12-AUG-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 report has been received from a physician, regarding a patient enrolled in an early access program concerning a male patient (age not provided).

No medical history was reported, and no concomitant products were reported.

On an unknown date the patient started treatment with Tagrisso (osimertinib) (batch number(s) UNK) 80 milligram qd, Oral use, for non-small cell lung cancer. On an unknown date, the patient experienced the patient developed pneumonitis during treatment with tagrisso (preferred term: Pneumonitis).

On an unspecified date the patient died from the event the patient developed pneumonitis during treatment with tagrisso.

It was unknown if any action was taken with Tagrisso.

It was not known whether an autopsy was performed. The cause of death was the patient developed pneumonitis during treatment with tagrisso.

The reporter assessed the event of he patient developed pneumonitis during treatment with tagrisso as serious due to death criterion.

The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event: the patient developed pneumonitis during treatment with tagrisso.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event: the patient developed pneumonitis during treatment with tagrisso.

Company Clinical Comment: Pneumonitis is a listed adverse event of Osimertinib. However, as the serious adverse event is reported with the seriousness criteria of death the event is considered unlisted. Underlying non-small cell lung cancer could be a possible contributing risk factor for the event. Due to limited information on other circumstances leading to the fatal event, start date of suspect drug, onset date of the event, clinical course and treatment provided for the event prior fatal outcome, relevant medical history, concurrent conditions and concomitant medications, recent status of underlying malignancy, detailed etiological and diagnostic workup prior fatal outcome, autopsy report if performed, the evaluation did not find evidence to suggest a causal relationship between the fatal event and the suspect drug.