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		67 Years	Male	Unk		JAN	2025

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
Death [Death]	TAGRISSO	Yes	No	Not Applicable	Not Related
Colitis [Colitis]	TAGRISSO	Yes	No	Not Applicable	Related
abdominal distension [Abdominal distension]	TAGRISSO	No	No	Not Applicable	Not Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 31-JUL-2025
- ☐ 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

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

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

17. INDICATION(S) FOR USE
#1) Unknown

18. THERAPY DATES(from/to)
#1) 17-FEB-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 neoplasm malignant (Lung neoplasm malignant)
Unknown to Ongoing	Indication	Lung neoplasm malignant (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-202503CAM004999CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00823218A

24b. MFR CONTROL NO.
202503CAM004999CR

24c. DATE RECEIVED BY MANUFACTURER
31-JUL-2025

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

DATE OF THIS REPORT
25-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Diarrhea [Diarrhoea]	TAGRISSO	No	Yes	Not Applicable	Not Related
Weight loss (from january 2025 to march 2025 10kg)/low weight [Weight decreased]	TAGRISSO	Yes	No	Related	Related
Many of flatulence [Flatulence]	TAGRISSO	No	No	Not Applicable	Not Related
Cansancio/lot of tiredness [Fatigue]	TAGRISSO	No	No	Related	Related
Vómitos [Vomiting]	TAGRISSO	No	No	Related	Related
nausea [Nausea]	TAGRISSO	No	No	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a male elderly patient born in 1957 (age 67 years).

The patient's past and current medical history included radiotherapy (dates not reported).

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib mesilate) 80 milligram qd, Oral use, on 17-FEB-2023 for lung neoplasm malignant.

During 15-JAN-25, the patient experienced weight loss (from january 2025 to march 2025 10kg)/low weight (preferred term: Weight decreased). On an unknown date, the patient experienced abdominal distension (preferred term: Abdominal distension), nausea (preferred term: Nausea), vómitos (preferred term: Vomiting), cansancio/lot of tiredness (preferred term: Fatigue), many of flatulence (preferred term: Flatulence), colitis (preferred term: Colitis) and diarrhea (preferred term: Diarrhoea).

It is unknown if any action was taken with Tagrisso (osimertinib mesilate).

The patient recovered from the event(s) weight loss (from january 2025 to march 2025 10kg)/low weight on an unspecified date. At the time of reporting, the event cansancio/lot of tiredness, nausea and vómitos was improving. At the time of reporting, the event abdominal distension, colitis, diarrhea and many of flatulence was ongoing. The patient died (preferred term: Death) on 31-JUL-2025.

The patient died on 31-JUL-2025. It is not known whether an autopsy was performed. The cause of death was unknown.

The following event(s) were considered serious due to death:death. The following event(s) were considered serious due to medically significant:weight loss (from january 2025 to march 2025 10kg)/low weight and colitis.

The following events were considered non-serious:abdominal distension, cansancio/lot of tiredness, diarrhea, many of flatulence, nausea and vómitos.

The reporter did not assess causality for abdominal distension, colitis, death, diarrhea and many of flatulence.The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): cansancio/lot of tiredness, nausea, vómitos and weight loss (from january 2025 to march 2025 10kg)/low weight.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): abdominal distension, death, diarrhea and many of flatulence. The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): cansancio/lot of tiredness, colitis, nausea, vómitos and weight loss (from january 2025 to march 2025 10kg)/low weight.

Summary of follow-up information received by AstraZeneca 28-Mar-2025: patient as new primary reporter added, new events of weight loss (from january 2025 to march 2025 10kg) and many of flatulence and colitis added, Narrative updated.

Corrected Report 01-Apr-2025: Country of patient changed from United States to Costa Rica.

Summary of follow up information received by AstraZeneca/ Medimmune 30-APR-2025 from Patient via Patient Support Program source: Description as Reported Weight loss was updated. Outcome of Weight loss was updated to Recovered. New events Fatigue, Vomiting, Nausea was added. Event assessment was added. RC/DC was added. Narrative updated.

Summary of follow-up information received by AstraZeneca on 31-Jul-2025 from other caregiver via a patient support program: New event of Death added. Action taken for the suspect drug of Tagrisso was updated as unknown from no change. Narrative amended.

Company Clinical Comment: Weight decreased and colitis are not listed in company core data sheet of Osimertinib. History of radiotherapy and underlying malignancy could be confounding. Due to limited information on circumstances leading to the events, start date and action taken of suspect drug, onset date and outcome of events, clinical course, treatment provided, concurrent conditions, risk factors, relevant medical history, detailed etiological and diagnostic work up, the evaluation did not find evidence to exclude a causal relationship between the events and suspect drug.

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Radiotherapy (Radiotherapy);