

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 64 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			PRIVACY					21	MAR	2025	

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
Death (unknown cause) [Death]	OSIMERTINIB	Yes	No	Related	Not Related
fatigue, my body feels heavy [Fatigue]	OSIMERTINIB	No	No	Related	Related

(Continued on Additional Information Page)

☒ PATIENT DIED
Date: 30-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) OSIMERTINIB (OSIMERTINIB) Tablet {Lot # Unknown}		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
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)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 21-MAR-2025 / Ongoing	19. THERAPY DURATION #1) Unknown	

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 Unknown to Ongoing	Type of History / Notes Indication	Description Lung cancer (Lung neoplasm malignant)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202503CAM021965CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00835563A
	24b. MFR CONTROL NO. 202503CAM021965CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 01-AUG-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 05-AUG-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Case Description: A solicited report has been received from a non-health professional in Patient Support Program. The report concerns a female adult patient born in 1960 (age 64 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Osimertinib (osimertinib) (batch number(s) Unknown) 80 milligram qd, Oral use, on 21-MAR-2025 for lung cancer.

On 21-MAR-25, the patient experienced fatigue, my body feels heavy (preferred term: Fatigue).

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

At the time of reporting, the event fatigue, my body feels heavy was ongoing. The patient died (preferred term: Death) on 30-JUL-2025.

The patient died on 30-JUL-2025. It is not known whether an autopsy was performed. The cause of death was death.

The following event(s) were considered serious due to death:death (unknown cause).

The following event was considered non-serious:fatigue, my body feels heavy.

The reporter considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event (s): death (unknown cause) and fatigue, my body feels heavy.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): death (unknown cause). The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): fatigue, my body feels heavy.

Summary of follow up information received by AstraZeneca/MedImmune on 01-AUG-2025 from consumer via patient support program source: New event death added, action taken updated. Narrative updated.

Company Clinical Comment: This case concerns a 64 year old female patient with fatal outcome in association with osimertinib. The cause of death was not further specified. Patient's underlying lung cancer could be confounding to patient's death. However, due to limited information on the exact cause of death, circumstances leading to death, status of underlying disease, concurrent diseases, concomitant medication, medical history, diagnostic workup prior fatal outcome, autopsy report (if performed), the evaluation did not find evidence to suggest a reasonable possibility of a causal relationship between fatal outcome and the suspect drug.