

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
		<b>PRIVACY</b>			<b>Unk</b>	<b>Female</b>	<b>Unk</b>		<b>Unk</b>		
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 (cause unknown) [Death]		OSIMERTINIB		Yes	No	Not Applicable	Not Related				
(Continued on Additional Information Page)											<input checked="" type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) OSIMERTINIB (OSIMERTINIB) Tablet		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input 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 ) (Not Coded)		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 ) Unknown	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 #: DO-ASTRAZENECA-202505CAM005745DO Study ID: PSP-23269 Case References: DO-AstraZeneca-CH-00866122A
	24b. MFR CONTROL NO. <b>202505CAM005745DO</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>08-MAY-2025</b>	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT <b>12-MAY-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

12-May-2025 14:09

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

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female patient (age not provided).

No medical history was reported. No concomitant products were reported.

On an unknown date the patient started treatment with Osimertinib (osimertinib) 80 milligram qd, Oral use for unknown indication.

It was unknown if any action was taken with Osimertinib.

On an unspecified date the patient died (preferred term: Death).

The patient died on an unknown date. It was not known whether an autopsy was performed. The cause of death was unknown.

The reporter assessed the event of death (cause unknown) as serious due to seriousness criteria of fatal outcome.

The reporter did not assess causality for death (cause unknown).

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