CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	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	
PRIVACY	PANAMA		PRIVACY		45 Years	Female	Unk		Unk		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
Neuropathy [Neuropathy]
Hallucinations [Hallucinations]
Edema [Edema]
Weight gain [Weight gain]

Case Description: This is a spontaneous report received from a Physician from a sales representative.

A 45-year-old female patient (not pregnant) received lorlatinib

(Continued on Additional Information Page)

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Lorbrena (LORLATINIB) Film-coated tablet

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1) 50 mg

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) ALK-Positive Lung Cancer (Lung neoplasm malignant)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)
#1) 01-JAN-2025 / 03-JUL-2025

19. THERAPY DURATION
#1) 6 months 3 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ALECTINIB (ALECTINIB) ; Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
202500137117

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
08-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

(LORBRENA), from 01Jan2025 to 03Jul2025 at 50 mg for lung neoplasm malignant. The patient's relevant medical history was not reported. Concomitant medication(s) included: ALECTINIB.
The following information was reported: NEUROPATHY PERIPHERAL (medically significant), outcome "not recovered", described as "Neuropathy"; HALLUCINATION (medically significant), outcome "not recovered", described as "Hallucinations"; OEDEMA (non-serious), outcome "not recovered", described as "Edema"; WEIGHT INCREASED (non-serious), outcome "not recovered", described as "Weight gain". The action taken for lorlatinib was unknown. It was unknown if therapeutic measures were taken as a result of neuropathy peripheral, hallucination, oedema, weight increased.

No follow-up attempts are possible.

Case Comment: Patients with lung malignancy can develop peripheral neuropathy as a direct effect of the cancer by invasion or compression of nerves,or paraneoplastic effect, hence causality for event peripheral neuropathy assessed as not related to lorlatinib.
Hallucinations can occur in patients of lung cancer,when the cancer has spread to the brain, hence not related to lorlatinib.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate