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	DOMINICAN REPUBLIC		PRIVACY		63 Years	Male	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
Patient died [Unknown cause of death]

Case Description: Safety information originally reported under manufacturer case 202500117748 has been nullified and re-entered under this new manufacturer report number 202500122552.

This is a spontaneous report received from a Consumer or other non HCP.

A 63-year-old male patient received lorlatinib (LORBRENA), since

(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

15. DAILY DOSE(S)
#1) UNK

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

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

18. THERAPY DATES(from/to)
#1) MAY-2024 / 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

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.
202500122552

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

24c. DATE RECEIVED BY MANUFACTURER
12-JUN-2025

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

DATE OF THIS REPORT
17-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

May2024. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEATH (death, medically significant), outcome "fatal", described as "Patient died". The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed..

Clinical information: It was unknown if the patient was taking any other medications within 2 weeks of the event starting.

No follow-up attempts are possible.

Follow-up (12Jun2025): This is a follow-up report to notify that the case 202500122552 and 202500117748 are duplicates. All subsequent follow-up information will be reported under manufacturer report number 202500122552.