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		
		Day	Month	Year				Day	Month	Year
PRIVACY	PANAMA		PRIVACY		43 Years	Female	Unk		MAR	2022

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

the patient died [Unknown cause of death]
Hemoglobin loss [Hemoglobin low]
Much calcium in blood [Calcium blood increased]
Ulcer [Ulcer]

Case Description: This is a spontaneous report and received from Consumer or other non HCPs, Program ID: 164974.

A 43-year-old female patient received lorlatinib (LORBRENA), from Dec2021 to Mar2022 at 100 mg 1x/day.

(Continued on Additional Information Page)

- ☒ PATIENT DIED Date: 2022
- ☒ 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) 100 mg, 1x/day

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

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

18. THERAPY DATES(from/to)
#1) DEC-2021 / MAR-2022

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)
#1) MORPHINE (MORPHINE) ; Unknown
#2) GABAPENTIN (GABAPENTIN) ; 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.
202200524088

24c. DATE RECEIVED BY MANUFACTURER
27-MAY-2025

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

DATE OF THIS REPORT
29-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

Mfr. Control Number: 202200524088

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history was not reported. Concomitant medication(s) included: MORPHINE; GABAPENTIN. The patient also took other concomitant therapy.
The following information was reported: BLOOD CALCIUM INCREASED (hospitalization) with onset Mar2022, 3 months after the suspect product(s) administration, outcome "unknown", described as "Much calcium in blood"; ULCER (non-serious) with onset Mar2022, 3 months after the suspect product(s) administration, outcome "unknown"; DEATH (death) with onset 2022, outcome "fatal", described as "the patient died"; HAEMOGLOBIN DECREASED (hospitalization), outcome "unknown", described as "Hemoglobin loss". The patient also had bedridden 3 months after the suspect product(s) administration. On 26May2025, the patient's husband confirmed that the patient died 3 years ago, the husband indicated that he cannot provide further details since he does not have the knowledge of the information. The patient underwent the following laboratory tests and procedures: Blood calcium: (Mar2022) much calcium in blood; Haemoglobin: (unspecified date) loss. The patient date of death was 2022. The reported cause of death was unknown.

Amendment: This follow-up report is being submitted to amend previously reported information: Case closure was handled as significant follow-up information. This follow-up is being submitted to notify that the batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Follow-up (27May2025): This is a spontaneous follow-up report received from a non contactable consumer. Updated information includes: new reporter added, suspect product details (action taken updated), new event of Death added, along with death details, and clinical course details.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAR-2022	Blood calcium	much calcium in blood	
2		Haemoglobin	loss	