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	COSTA RICA		PRIVACY		65 Years	Female	Unk		JUL	2024	

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
recurrence of cancer, comments that the cancer increased / the disease that advanced [Lung cancer]
recurrence of cancer, comments that the cancer increased / the disease that advanced [Malignant neoplasm progression]
recurrence of cancer, comments that the cancer increased / the disease that advanced [Lung cancer recurrent]
Fatigued [Fatigue]
has also gained 2 kg of weight [Weight gain]
pain [Pain]

(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) 100 mg, 1x/day

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

17. INDICATION(S) FOR USE
#1) lung cancer (Lung neoplasm malignant)

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.
PV202400116617

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

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

DATE OF THIS REPORT
20-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

stiffness in her hands [Stiffness]
stiffness in her hands and feels stiff there are days when it is so strong that she it can not move them [Mobility decreased]

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

A 65-year-old female patient received lorlatinib (LORBRENA), since May2024 at 100 mg 1x/day for lung neoplasm malignant. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PAIN (non-serious) with onset Jul2024, outcome "unknown"; LUNG NEOPLASM MALIGNANT (medically significant), MALIGNANT NEOPLASM PROGRESSION (medically significant), LUNG CARCINOMA CELL TYPE UNSPECIFIED RECURRENT (medically significant) all with onset Jul2024, outcome "unknown" and all described as "recurrence of cancer, comments that the cancer increased / the disease that advanced"; MUSCULOSKELETAL STIFFNESS (non-serious) with onset Jul2024, outcome "unknown", described as "stiffness in her hands"; MOBILITY DECREASED (non-serious) with onset Jul2024, outcome "unknown", described as "stiffness in her hands and feels stiff there are days when it is so strong that she it can not move them"; FATIGUE (non-serious), outcome "unknown", described as "Fatigued"; WEIGHT INCREASED (non-serious), outcome "unknown", described as "has also gained 2 kg of weight". Clinical course: Nurse reported that patient had felt more fatigued since she started treatment and has also gained 2 kg of weight for two months, she has pain, stiffness in her hands and feels stiff there are days when it is so strong that she can not move them. As of 19may2025, the patient indicated that they suspended treatment with Lorbrena because there was a recurrence of cancer, comments that the cancer increased, therefore, the doctor decided to suspend the treatment. The treatment was provided in PRIVACY but having the disease that advanced again, Lorbrena was suspended. The action taken for lorlatinib was temporarily withdrawn.

Follow-up (05Nov2024): Follow-up attempts are completed.

Follow-up (19May2025): This is a spontaneous follow-up report received from a contactable consumer (patient).
Updated information: case is upgraded to serious, new reporter (consumer), suspect drug data (updated action taken), reaction data (added Lung neoplasm malignant, Malignant neoplasm progression, Lung carcinoma cell type unspecified recurrent), and course of therapy.