# 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 | | 70 Years | Female | Unk | 07 | JUL | 2025 |

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
suicidal ideation [Suicidal ideation]
significant increase in cholesterol [Blood cholesterol increased]
She now depends on help from her family [Loss of personal independence in daily activities]
dramatic deterioration in her quality of life [Impaired quality of life]
reduced mobility, need for a cane and walker [Mobility decreased]
constant pain [Pain]
extreme fatigue [Fatigue extreme]
lower back pain [Low back pain]

**(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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

**(Continued on Additional Information Page)**

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

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) 100 mg | #1 ) Unknown |

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

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) Unknown | #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 | 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.
**PV202500082233**

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: PV202500082233

## ADDITIONAL INFORMATION

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

memory loss [Memory loss]
joint pain [Joint pain]
sensitivity in the palms of her hands [Increased skin sensitivity]

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

A 70-year-old female patient received lorlatinib (LORBRENA), first regimen at 100 mg and second regimen at 50 mg. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (medically significant) with onset 07Jul2025 at 16:00, outcome "unknown", described as "She now depends on help from her family"; ARTHRALGIA (non-serious) with onset 07Jul2025 at 16:00, outcome "unknown", described as "joint pain"; BACK PAIN (non-serious) with onset 07Jul2025 at 16:00, outcome "unknown", described as "lower back pain"; SENSITIVE SKIN (non-serious) with onset 07Jul2025 at 16:00, outcome "unknown", described as "sensitivity in the palms of her hands"; SUICIDAL IDEATION (medically significant), outcome "unknown"; BLOOD CHOLESTEROL INCREASED (medically significant), outcome "unknown", described as "significant increase in cholesterol"; IMPAIRED QUALITY OF LIFE (medically significant), outcome "unknown", described as "dramatic deterioration in her quality of life"; MOBILITY DECREASED (medically significant), outcome "unknown", described as "reduced mobility, need for a cane and walker"; PAIN (non-serious), outcome "unknown", described as "constant pain"; FATIGUE (non-serious), outcome "unknown", described as "extreme fatigue"; AMNESIA (non-serious), outcome "unknown", described as "memory loss".
Clinical information: The patient contacts the line to request program benefits. However, she mentions that she initially started with 100 mg and it was progressively reduced to 50 mg due to side effects she could not tolerate, including a significant increase in cholesterol. Despite stopping the medication for a month, the patient continues to experience debilitating symptoms such as reduced mobility, need for a cane and walker, constant pain, and extreme fatigue. She expresses deep frustration and despair over the dramatic deterioration in her quality of life. She now depends on help from her family and even experiences suicidal ideation as a side effect. She mentions that the ongoing struggle highlights the physical and emotional toll the medication has taken, significantly impacting her independence and overall well-being. The patient said that since she started taking the medication, she has experienced memory loss, lower back pain, joint pain, sensitivity in the palms of her hands, and increased cholesterol levels. The doctor suspended the medication for one month. It has been more than 15 days since it was suspended.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) Lorbrena (LORLATINIB) Film-coated tablet; Regimen #2 | 50 mg; Unknown | Unknown | Unknown;<br>Unknown |