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		47 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)

medication is significantly affecting her weight and triglyceride levels, as both have increased [Blood triglycerides increased]
medication is significantly affecting her weight and triglyceride levels, as both have increased [Weight increased]
it was difficult to breathe when she walks certain distances [Dyspnea on effort]
she could not walk a distance that would be considered running [Walking difficulty]

Case Description: This is a spontaneous report received from a Consumer

(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

(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, 1x/day	#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) JAN-2025 / 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.
PV202500086094

24c. DATE RECEIVED BY MANUFACTURER
11-AUG-2025

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

DATE OF THIS REPORT
14-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

or other non HCP, Program ID: 164974.

A 47-year-old female patient received lorlatinib (LORBRENA), first regimen since Jan2025 at 100 mg 1x/day and second regimen since 15Jul2025 (Lot number: RE1496449, Expiration Date: Feb2027) at 100 mg 1x/day. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: BLOOD TRIGLYCERIDES INCREASED (non-serious), WEIGHT INCREASED (non-serious), outcome "unknown" and all described as "medication is significantly affecting her weight and triglyceride levels, as both have increased"; DYSPNOEA EXERTIONAL (non-serious), outcome "unknown", described as "it was difficult to breathe when she walks certain distances"; GAIT DISTURBANCE (non-serious), outcome "unknown", described as "she could not walk a distance that would be considered running". Relevant laboratory tests and procedures are available in the appropriate section. The action taken for lorlatinib was unknown.

Additional information: The patient indicated that the medication was significantly affecting her weight and triglyceride levels, as both have increased. She mentioned that these are the two most serious side effects. On 11Aug2025 patient reported that she had a health condition, which was ALK -positive lung cancer, but she was finding it difficult to breathe when she walked certain distances. When she walked a certain distance, she had to stop because she would get short of breath. It was a situation that did not allow her to walk continuously, and she could not walk a distance that would be considered running.

Follow-up (11Aug2025): This is a spontaneous follow-up report received from a Consumer or other non HCP, Program ID: 164974
Updated information: New events coded (Dyspnea on effort and Walking Difficulty)

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood triglycerides	Increased	

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Lorbrena (LORLATINIB) Film-coated tablet {Lot # RE1496449; Exp.Dt. FEB-2027}; Regimen #2	100 mg, 1x/day; Unknown	Unknown	15-JUL-2025 / Unknown; Unknown