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]

Case Description: This is a spontaneous report received from a Consumer 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 **(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
15-JUL-2025

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

DATE OF THIS REPORT
21-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: PV202500086094

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

(Lot number: RE1496449, Expiration Date: Jan2027) 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". 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.

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. JAN-2027}; Regimen #2	100 mg, 1x/day; Unknown	Unknown	15-JUL-2025 / Unknown; Unknown