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	COSTA RICA		PRIVACY		Unk	Male	Unk		Unk	

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
increase in triglycerides to 1500 [Triglyceride increased]

Case Description: This is a spontaneous report received from a Physician.

A male patient received lorlatinib (LORBRENA), at 100 mg daily for lung cancer.

(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

15. DAILY DOSE(S)
#1) 100 mg, daily

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

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

18. THERAPY DATES(from/to)
#1) 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.
202500172212

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

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

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

DATE OF THIS REPORT
01-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202500172212

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: BLOOD TRIGLYCERIDES INCREASED (medically significant), outcome "recovering", described as "increase in triglycerides to 1500". The patient had been taking LORBRENA for one month and experienced an increase in triglycerides to 1500. The action taken for lorlatinib was unknown.

No follow-up attempts are possible.

Case Comment: Based on the known drug safety profile and implied temporal association, a causal relationship between suspect drug and reported event Blood triglycerides increased is assessed as related.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood triglycerides increase	1500	