

## SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>DOMINICAN REPUBLIC</b>	2. DATE OF BIRTH Day Month Year <b>PRIVACY</b>			2a. AGE <b>63</b> Years	3. SEX <b>Male</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET Day Month Year <b>Unk</b>			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input checked="" type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) <b>Other Serious Criteria: Medically Significant</b> <b>Patient died [Unknown cause of death]</b>  Case Description: This is a spontaneous report received from a Consumer or other non HCP.  A 63-year-old male patient received lorlatinib (LORBRENA), since May2024.  <b>(Continued on Additional Information Page)</b>											

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) Lorbrena (LORLATINIB) Film-coated tablet</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) UNK</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Unknown</b>	
17. INDICATION(S) FOR USE <b>#1 ) Unknown</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) MAY-2024 / Unknown</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## 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 <b>Unknown</b>		

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Pfizer S.A. Laura Arce Mora Avenida Escazú, Torre Lexus, piso 7. Escazú San Jose, COSTA RICA</b>		26. REMARKS
24b. MFR CONTROL NO. <b>202500117748</b>		
24c. DATE RECEIVED BY MANUFACTURER <b>09-JUN-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT <b>11-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	
25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>		

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**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: DEATH (death, medically significant), outcome "fatal", described as "Patient died". The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

Clinical information: It was unknown if the patient was taking any other medications within 2 weeks of the event starting.

No follow-up attempts are possible.