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		66 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)

Other Serious Criteria: Medically Significant
Diabetes [Diabetes]
problem she has in her brain [Brain disorder NOS]
Blood pressure pill [Blood pressure abnormal]

Case Description: This is a spontaneous report received from a , Program ID: 164974.

A 66-year-old female patient received axitinib (INLYTA), at 5 mg.

(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) Inlyta (AXITINIB) Film-coated tablet

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 5 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.
PV202500063197

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

24c. DATE RECEIVED BY MANUFACTURER
22-MAY-2025

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

DATE OF THIS REPORT
30-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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: DIABETES MELLITUS (medically significant), outcome "unknown", described as "Diabetes"; CEREBRAL DISORDER (non-serious), outcome "unknown", described as "problem she has in her brain"; BLOOD PRESSURE ABNORMAL (non-serious), outcome "unknown", described as "Blood pressure pill". The action taken for axitinib was unknown. Therapeutic measures were taken as a result of diabetes mellitus, cerebral disorder, blood pressure abnormal.

Clinical course: Patient caregiver indicated; She is taking a blood pressure pill. In total, he takes three medications: one for blood pressure, one for diabetes and one prescribed for a problem he has in his brain." When asked if he uses inlyta, he does not confirm it and does not specify what he means by a brain problem. The adverse event is reported because it is not possible to confirm information.

No follow-up attempts are possible.