# 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 | | 84 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
mother has already died [Unknown cause of death]
Fatigue/Mild tiredness [Fatigue]
Loss of appetite [Appetite lost]
Moderate weakness [Weakness]
Mild pain [Pain]

Case Description: This is a spontaneous report received from a Nurse and a Consumer or other non HCP, Program ID: 164974.

**(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 ) Inlyta (AXITINIB) Film-coated tablet {Lot # GR8549; Exp.Dt. AUG-2025}

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

15. DAILY DOSE(S)
#1 ) 5 mg, 2x/day

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

17. INDICATION(S) FOR USE
#1 ) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

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

19. THERAPY DURATION
#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.
**PV202300162261**

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

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

DATE OF THIS REPORT
20-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

An 84-year-old female patient received axitinib (INLYTA, strength: 5 mg), (Lot number: GR8549, Expiration Date: Aug2025) at 5 mg 2x/day, oral. 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 "mother has already died"; FATIGUE (non-serious), outcome "recovering", described as "Fatigue/Mild tiredness"; DECREASED APPETITE (non-serious), outcome "recovering", described as "Loss of appetite"; ASTHENIA (non-serious), outcome "recovering", described as "Moderate weakness"; PAIN (non-serious), outcome "unknown", described as "Mild pain". The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.

Clinical course: The reported issues occurred after use of the product. No admission to hospital due to the events. The patient presented mild adverse events, which were managed at home efficiently, being able to control the reported symptoms. On 19May2025 the patient's daughter stated "are you from the hospital's patient program? I find it strange that you don't know that my mother has already died and I would not like to talk about what happened." Patient's daughter does not provide further details. A report was made since it is not possible to identify if it was within the consumption of the medicines. Take into account that in the system the patient is enrolled with Inlyta 5mg and Sutent 50mg.

Follow-up (01Nov2023): This is a spontaneous follow-up report received from the same contactable reporter (Nurse).
Updated information: Route of administration and action taken of axitinib; outcome of events "Fatigue/Mild tiredness", "Loss of appetite" and "Moderate weakness'.

Follow-up attempts are completed. No further information is expected.

Follow-up (19May2025): This is a spontaneous follow-up report received from the same contactable consumer.

Updated information included: reporter details, action taken, new event added (Unknown cause of death) and clinical course details. Case is now serious.

Case Comment: Based on the information available, the death of unknown cause is assessed by the Company as related to the suspect drug axitinib as a cautionary measure and for reporting purposes until sufficient information becomes available. The patient's underlying disease may provide an alternative explanation for the event.
The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.