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		83 Years	Female	Unk		APR	2023

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
already died [Unknown cause of death]
She was almost killed by it/She almost died [Near death experience]
Fractured a month ago [Fracture]
muscle weakness/ such an extent muscle weakness that does not mobilize [Muscle weakness]
muscle weakness/ such an extent muscle weakness that does not mobilize [Mobility decreased]
very drowsy [Drowsiness]
sugar spikes that she did not have before (very strong)/ low sugar levels

(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) Sutent (SUNITINIB MALATE) Capsule, hard {Lot # FW0017; Exp.Dt. SEP-2024}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) One week ta (Continued on Additional Information Page)

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

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

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

18. THERAPY DATES(from/to)
#1) Unknown / MAY-2023

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.
PV202300090041

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

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

DATE OF THIS REPORT
21-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
(Continued on Additional Information Page)

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

presenting 58mg / dL of sugar [Blood sugar decreased]
high blood pressure [Blood pressure high]
too much fatigue/ chronic fatigue [Fatigue]
insomnia [Insomnia]
ear pain [Ear pain]
pain in the mouth/ pain in the mouth in general, in the gums [Mouth pain]
pain in the mouth in general, in the gums [Pain gum]
pain in the teeth until she feel loose teeth [Tooth pain]
loose teeth [Loose tooth]
mental confusion [Mental confusion]
it has not been well at all [Unwell]
Drug intolerance [Drug intolerance]
One week takes the medicine and another week rests [Off label dosing frequency]

Case Description: The initial safety information received was reporting only non-serious adverse drug reactions. Upon receipt of follow up information on 18May2023, this case contains serious adverse reaction and all safety information is processed together.

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

An 83-year-old female patient (not pregnant) received sunitinib malate (SUTENT), (Lot number: FW0017, Expiration Date: Sep2024) till May2023 at 50 mg cyclic (one week take the medicine and another week rest (one daily dose)). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: FRACTURE (medically significant) with onset Apr2023, outcome "unknown", described as "Fractured a month ago"; DEATH (death, medically significant), outcome "fatal", described as "already died"; NEAR DEATH EXPERIENCE (life threatening), outcome "unknown", described as "She was almost killed by it/She almost died"; MUSCULAR WEAKNESS (non-serious), MOBILITY DECREASED (non-serious), outcome "unknown" and all described as "muscle weakness/ such an extent muscle weakness that does not mobilize"; SOMNOLENCE (non-serious), outcome "unknown", described as "very drowsy"; BLOOD GLUCOSE DECREASED (non-serious), outcome "unknown", described as "sugar spikes that she did not have before (very strong)/ low sugar levels presenting 58mg / dL of sugar"; HYPERTENSION (non-serious), outcome "unknown", described as "high blood pressure"; FATIGUE (non-serious), outcome "unknown", described as "too much fatigue/ chronic fatigue"; INSOMNIA (non-serious), outcome "unknown"; EAR PAIN (non-serious), outcome "unknown"; ORAL PAIN (non-serious), outcome "unknown", described as "pain in the mouth/ pain in the mouth in general, in the gums"; GINGIVAL PAIN (non-serious), outcome "unknown", described as "pain in the mouth in general, in the gums"; TOOTHACHE (non-serious), outcome "unknown", described as "pain in the teeth until she feel loose teeth"; LOOSE TOOTH (non-serious), outcome "unknown", described as "loose teeth"; CONFUSIONAL STATE (non-serious), outcome "unknown", described as "mental confusion"; MALAISE (non-serious), outcome "unknown", described as "it has not been well at all"; DRUG INTOLERANCE (non-serious), outcome "unknown"; OFF LABEL USE (non-serious), outcome "unknown", described as "One week takes the medicine and another week rests". The patient underwent the following laboratory tests and procedures: Blood glucose: 58 mg/dl, notes: Low. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed. The action taken for sunitinib malate was not applicable.
Clinical course: Consumer stated this week was the week of rest and it had not been well at all. The patient did not tolerate the medication. Nurse indicated that the patient was taking one pill a day of Sutent and was taking it for a week, she took it for a week and due to adverse effects she stopped it on the recommendation of the oncologist for one month, this was the fourth day of discontinuation of treatment. The symptoms or side effects that the patient had presented have been: insomnia, ear pain, low sugar levels presenting 58 mg/dL of sugar, pain in the mouth, pain in the teeth until she feel loose teeth, pain in the mouth in general, in the gums, muscle weakness and chronic fatigue to such an extent muscle weakness that does not mobilize, the patient was in a wheelchair and as nurse was told before she had independent mobility, she moved alone, in addition she has presented mental confusion. The patient fractured a month ago, so she's in a wheelchair, but nurse didn't know if it was the hip or the knee that was fractured. As of 25Sep2023, the patient's daughter reported: "She was taking another treatment previously, but she did not resist it. That treatment was already been taken away at the hospital, but that was a long time ago. She was almost killed by it. It is called sunitinib. She had to increase the dose, and within a week, she almost died". "Drug intolerance" was also reported. The physician changed the therapy to INLYTA. The patient was then taking the second immunotherapy, and in combination with INLYTA 5 mg. On 19May2025, patient's daughter indicated that her mother has already died.

Follow-up (05Jul2023): Follow-up attempts are completed. No further information is expected.

Follow-up (25Sep2023): This is a spontaneous follow-up report received from a Consumer or other non-HCP (patient's daughter), Program ID: (164974).
Updated information included: new reporter (patient's daughter). Action taken was updated to permanently withdrawn. New event of "She was almost killed by it/She almost died".

Follow-up (28Sep2023): This is a spontaneous follow-up report received from a Consumer or other non-HCP. Updated information included: new event of "Drug intolerance".

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Updated information: new reporter (consumer), action taken updated, new event unknown cause of death, clinical course.

Case Comment: Fracture is most likely related to intercurrent or underlying conditions and unrelated to subject drug SUNITINIB MALATE. 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.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose Low	58 mg/dl	

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) Sutent (SUNITINIB MALATE) Capsule, hard {Lot # FW0017; Exp.Dt. SEP-2024}; Regimen #1	One week take the medicine and another week rest (one daily dose); Unknown	Unknown	Unknown / MAY-2023; Unknown

25b. Name And Address of Reporters continued
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.