CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		Unk	Female	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Upper respiratory infection [Upper respiratory tract infection]	SAPHNELO	No	Yes		
Fracture of tibia [Tibia fracture]	SAPHNELO	Yes	No		
Fracture of fibula [Fibula fracture]	SAPHNELO	Yes	No		

(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
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) SAPHNELO (ANIFROLUMAB) Solution for injection

15. DAILY DOSE(S)
#1) 300 milligram, qmonth

16. ROUTE(S) OF ADMINISTRATION
#1) Intravenous use

17. INDICATION(S) FOR USE
#1) Systemic lupus erythematosus (Systemic lupus erythematosus)

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 to Ongoing	Indication	Systemic lupus erythematosus (Systemic lupus erythematosus)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: GT-ASTRAZENECA-202507CAM013109GT
Case References: GT-AstraZeneca-CH-00912194A

24b. MFR CONTROL NO.
202507CAM013109GT

24c. DATE RECEIVED BY MANUFACTURER
15-JUL-2025

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

DATE OF THIS REPORT
22-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a consumer concerning a female patient (age not provided).

No medical history and concomitant products were reported.

On an unknown date, the patient started treatment with Saphnelo (anifrolumab) 300 milligram qmonth, Intravenous use, for systemic lupus erythematosus.

On an unknown date, the patient experienced fracture of tibia (preferred term: Tibia fracture), fracture of fibula (preferred term: Fibula fracture) and upper respiratory infection (preferred term: Upper respiratory tract infection).

Treatment with Saphnelo was temporarily Withdrawn.

The outcome of the events of fracture of fibula, fracture of tibia and upper respiratory infection was unknown.

The following events were considered serious due to medically significant: fracture of fibula and fracture of tibia.

The following event was considered non-serious: upper respiratory infection.

Company Clinical Comment: Tibia fracture and Fibula fracture are not listed in the company core data sheet of anifrolumab. Underlying systemic lupus erythematosus and gender of patient could be considered as risk factors. Due to limited information on relevant medical history and concomitant medications, circumstances leading to the events, further risk factors, etiological and diagnostic workup, the evaluation did not find evidence to suggest a causal relationship between the events and the suspect drug.