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)

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		

(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) 06-JUN-2025 / 15-JUL-2025

19. THERAPY DURATION
#1) 40 days

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-202507CAM012950GT
Case References: GT-AstraZeneca-CH-00912163A

24b. MFR CONTROL NO.
202507CAM012950GT

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

NAME AND ADDRESS WITHHELD.

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:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a physician. The report concerns a female patient (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Saphnelo (anifrolumab) 300 milligram qmonth, Intravenous use, on 06-JUN-2025 for systemic lupus erythematosus.

On an unknown date, the patient experienced upper respiratory infection (preferred term: Upper respiratory tract infection).
The last dose of SAPHNELO prior to onset was taken on 15-JUL-25.

Treatment with Saphnelo (anifrolumab) was temporarily Withdrawn.

The patient recovered from the event(s) upper respiratory infection on an unspecified date.

The event was considered non-serious.