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		29 Years	Female	Unk	14	JUL	2025

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
Fever [Pyrexia]	SAPHNELO	No	No	Related	Related

(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, q4w

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

17. INDICATION(S) FOR USE
#1) Lupus (Antiphospholipid antibodies)

18. THERAPY DATES(from/to)
#1) 14-JUL-2025 / 14-JUL-2025

19. THERAPY DURATION
#1) 1 day

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	Lupus erythematosus systemic (Systemic lupus erythematosus)
Unknown	Indication	Lupus anticoagulant (Antiphospholipid antibodies)

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-202507CAM025211GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00920902A

24b. MFR CONTROL NO.
202507CAM025211GT

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

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

DATE OF THIS REPORT
30-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 report has been received from a consumer, regarding a subject enrolled in study PSP- 23269, NA. The report concerns a female adult patient of Hispanic ethnic origin born in 1996 (age 29 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Saphnelo (anifrolumab) 300 milligram q4w, Intravenous use, on 14-JUL-2025 for lupus.

On 14-JUL-25, the patient experienced fever (preferred term: Pyrexia).
The last dose of SAPHNELO prior to onset was taken on 14-JUL-25.

The dose of Saphnelo (anifrolumab) was not changed.

The patient recovered from the event(s) fever after 1 day on 14-JUL-2025.

The event was considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): fever.
The company physician considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): fever.