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	COSTA RICA		PRIVACY		39 Years	Female	Unk	14	MAR	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
pain [Pain]	SAPHNELO	No	No	Related	Related
The doctor delayed the application of treatment for a week [Inappropriate schedule of product administration]	SAPHNELO	No	No	Not Applicable	Not Applicable
due to suspected herpes zoster [Herpes zoster]	SAPHNELO	No	Yes	Not Applicable	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 {Lot # Unknown}

15. DAILY DOSE(S)
#1) 300 milligram, q4w

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

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

18. THERAPY DATES(from/to)
#1) 14-MAR-2025 / 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	Lupus erythematosus (Systemic lupus erythematosus)
Unknown to Ongoing	Indication	Lupus syndrome (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 #: CR-ASTRAZENECA-202503CAM013477CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00829560A

24b. MFR CONTROL NO.
202503CAM013477CR

24c. DATE RECEIVED BY MANUFACTURER
21-AUG-2025

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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 solicited report has been received from a consumer in Patient Support Program. The report concerns a female adult patient born in 1985 (age 39 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Saphnelo (anifrolumab) (batch number(s) Unknown) 300 milligram q4w, Intravenous use, on 14-MAR-2025 for lupus.

On 14-MAR-25, the patient experienced fever (preferred term: Pyrexia) and pain (preferred term: Pain). On 20-AUG-25, the patient experienced due to suspected herpes zoster (preferred term: Herpes zoster) and the doctor delayed the application of treatment for a week (preferred term: Inappropriate schedule of product administration).

The report described a medication error for Saphnelo. The reported term was the doctor delayed the application of treatment for a week (preferred term: Inappropriate schedule of product administration).

Treatment with Saphnelo (anifrolumab) was temporarily Withdrawn.

The patient recovered from the event(s) fever and pain after 2 days on 16-MAR-2025. At the time of reporting, the event due to suspected herpes zoster and the doctor delayed the application of treatment for a week was improving.

The events were considered non-serious.

The reporter did not assess causality for due to suspected herpes zoster and the doctor delayed the application of treatment for a week.The reporter considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): fever and pain.
The company physician considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): due to suspected herpes zoster, fever and pain.

Summary of follow up information received by AstraZeneca on 21-AUG-2025 from consumer via Patient Support Program: The doctor delayed the application of treatment for a week due to suspected herpes zoster was added as new event. Action taken updated from unknown to Temporarily Withdrawn. Consent to follow-up with reporter updated as yes. Narrative updated.