# 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 | | 44 Years | Female | Unk | 13 | AUG | 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 |
|---|---|---|---|---|---|
| Herpes zoster [Herpes zoster] | SAPHNELO | No | Yes | 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 ) Unknown

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

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

18. THERAPY DATES(from/to)
#1 ) 15-MAY-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)
#1 ) Acyclovir (Aciclovir) ; Unknown
#2 ) Valganciclovir (Valganciclovir hydrochloride) ; Unknown

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 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 #: CR-ASTRAZENECA-202508CAM013470CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00933186A

24b. MFR CONTROL NO.
**202508CAM013470CR**

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

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

DATE OF THIS REPORT
22-AUG-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 solicited report has been received from a consumer in Patient Support Program. The report concerns a female adult patient born in 1981 (age 44 years).

No medical history was reported.

Concomitant medication included Acyclovir and Valganciclovir.

The patient started treatment with Saphnelo (anifrolumab) 300 milligram q4w, Intravenous use, on 15-MAY-2025 for lupus.

On 13-AUG-25, the patient experienced herpes zoster (preferred term: Herpes zoster).

Treatment with Saphnelo (anifrolumab) was temporarily Withdrawn.

At the time of reporting, the event herpes zoster was ongoing.

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): herpes zoster.

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