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	COSTA RICA		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
Very strong crisis (not specified) [Condition aggravated]	SAPHNELO	Yes	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 {Lot # Unknown}

15. DAILY DOSE(S)
#1) Unknown

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

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

18. THERAPY DATES(from/to)
#1) 19-FEB-2025 / Ongoing

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 (Systemic lupus erythematosus)
Unknown	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-202506CAM011074CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00891303A

24b. MFR CONTROL NO.
202506CAM011074CR

24c. DATE RECEIVED BY MANUFACTURER
13-JUN-2025

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

DATE OF THIS REPORT
17-JUN-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 non-health professional in Patient Support Program. The report concerned a female patient born in 1992.

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 19-Feb-2025 for lupus.

On an unknown date, the patient experienced very strong crisis (not specified) (preferred term: Condition aggravated).

The dose of Saphnelo (anifrolumab) was not changed.

At the time of reporting, the event very strong crisis (not specified) was improving.

The event was considered serious due to Medically Significant.

The reporter considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): very strong crisis (not specified).
The company physician considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): very strong crisis (not specified).

Company Clinical Comment: Condition aggravated [reported as very strong crisis] is not listed in company core data sheet of anifrolumab. Due to limited information on circumstances leading to the event, onset date of event, clinical course, treatment provided, concurrent conditions, concomitant medications, risk factors, relevant medical history, detailed etiological and diagnostic work up, the evaluation did not find evidence to exclude a causal relationship between the event and suspect drug.