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		36 Years	Female	Unk	18	NOV	2024

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
Eye infection [Eye infection]	ANIFROLUMAB	No	No	Not Applicable	Related
Lip infection [Lip infection]	ANIFROLUMAB	No	No	Not Applicable	Related
patient reports, this time my knees and hands are quite swollen. I applied it last Wednesday and this week I'm quite swollen [Peripheral swelling]	ANIFROLUMAB	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) ANIFROLUMAB (ANIFROLUMAB) Solution for injection

15. DAILY DOSE(S)
#1) 300 milligram per millilitre, 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) 23-OCT-2024 / 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 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-202411CAM020478CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00755235A

24b. MFR CONTROL NO.
202411CAM020478CR

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

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

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

DATE OF THIS REPORT
16-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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 1988 (age 36 years).

No medical history was reported. No concomitant products were reported.

The patient started treatment with Anifrolumab (anifrolumab) 300 milligram per millilitre q4w, Intravenous use, on 23-OCT-2024 for lupus.

On 18-NOV-24, the patient experienced eye infection (preferred term: Eye infection). On 25-NOV-24, the patient experienced lip infection (preferred term: Lip infection). On an unknown date, the patient experienced patient reports, this time my knees and hands are quite swollen. i applied it last wednesday and this week i'm quite swollen (preferred term: Peripheral swelling).

The dose of Anifrolumab (anifrolumab) was not changed. The outcome of the event(s) of eye infection and lip infection was unknown. At the time of reporting, the event patient reports, this time my knees and hands are quite swollen. i applied it last wednesday and this week i'm quite swollen was ongoing.

The events were considered non-serious.

The reporter did not assess causality for eye infection and lip infection. The reporter considered that there was a reasonable possibility of a causal relationship between Anifrolumab and the following event(s): patient reports, this time my knees and hands are quite swollen. i applied it last wednesday and this week i'm quite swollen.
The company physician considered that there was a reasonable possibility of a causal relationship between Anifrolumab and the following event(s): eye infection, lip infection and patient reports, this time my knees and hands are quite swollen. i applied it last wednesday and this week i'm quite swollen.

Summary of follow-up information received by AstraZeneca on 13-Jun-2025 from consumer via solicited source: new event (patient reports, this time my knees and hands are quite swollen. I applied it last Wednesday and this week I'm quite swollen) captured, action taken for Saphnelo updated from unknown to no change, route amended. Non-significant correction on 16-Jun-2025: non-English event terms were updated, study drug details captured.