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		51 Years	Female	85.00 kg	10	FEB	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
Feeling of intense fatigue [Fatigue]	ANIFROLUMAB	No	No	Related	Related
Headache [Headache]	ANIFROLUMAB	No	No	Related	Related
rashes on the face [Rash]	ANIFROLUMAB	No	No	Related	Related
Infectious-type folliculitis of the face and arms [Folliculitis]	ANIFROLUMAB	No	No	Related	Related
Joint pain (knees, fingers, wrists, hips, and feet) [Arthralgia]	ANIFROLUMAB	No	No	Related	Related
Facial injuries [Face injury]	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, q4w

16. ROUTE(S) OF ADMINISTRATION
#1) IV drip

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

18. THERAPY DATES(from/to)
#1) 10-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	Historical Condition	Erythromelalgia (Erythromelalgia)

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-202503CAM007362CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00824900A

24b. MFR CONTROL NO.
202503CAM007362CR

24c. DATE RECEIVED BY MANUFACTURER
14-MAY-2025

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

DATE OF THIS REPORT
20-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

25b. NAME AND ADDRESS OF REPORTER
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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 1973 (age 51 years, height 158 cm, weight 85 kg).

The patient’s past and current medical history included chronic fatigue (dates not reported), erythromelalgia (dates not reported), extreme photosensitivity (dates not reported) and raynaud's syndrome (dates not reported).

No concomitant products were reported.

The patient started treatment with Anifrolumab (anifrolumab) 300 milligram q4w, IV drip, on 10-FEB-2025 for lupus.

On 10-FEB-25, the patient experienced rashes on the face (preferred term: Rash) and infectious-type folliculitis of the face and arms (preferred term: Folliculitis). On 07-MAR-25, the patient experienced headache (preferred term: Headache) and feeling of intense fatigue (preferred term: Fatigue). On an unknown date, the patient experienced joint pain (knees, fingers, wrists, hips, and feet) (preferred term: Arthralgia) and facial injuries (preferred term: Face injury).

The dose of Anifrolumab (anifrolumab) was not changed.

The patient recovered from the event(s) feeling of intense fatigue and headache after 1 day on 08-MAR-2025. The patient recovered from the event(s) infectious-type folliculitis of the face and arms after 6 weeks on 25-MAR-2025. At the time of reporting, the event facial injuries, joint pain (knees, fingers, wrists, hips, and feet) and rashes on the face was ongoing.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Anifrolumab and the following event (s): facial injuries, feeling of intense fatigue, headache, infectious-type folliculitis of the face and arms, joint pain (knees, fingers, wrists, hips, and feet) and rashes on the face.
The company physician considered that there was a reasonable possibility of a causal relationship between Anifrolumab and the following event(s): facial injuries, feeling of intense fatigue, headache, infectious-type folliculitis of the face and arms, joint pain (knees, fingers, wrists, hips, and feet) and rashes on the face.

Summary of follow-up information received by Astrazeneca on 19-MAR-2025 from Consumer via solicited report: medical history added, new event of rashes on the face added, outcome, causality, dechallange, rechallenge updated. Narrative amended.

Summary of follow-up information received by Astrazeneca on 25-MAR-2025 from Consumer via solicited report: Action taken for suspect product was updated to no change. Route of administration was updated to IV drip. New non-serious event of Infectious-type folliculitis of the face and arms was added. Dechallenge updated. Narrative updated.

Summary of follow up information received by AstraZeneca on 14-May-2025 from consumer via Patient Support Program: New Events Joint pain (knees, fingers, wrists, hips, and feet),Facial injuries . Narrative updated.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Raynaud's syndrome (Raynaud's phenomenon);
Unknown	Historical Condition	Photosensitivity (Photosensitivity reaction);
Unknown	Historical Condition	Chronic fatigue (Fatigue);
Unknown to Ongoing	Indication	Systemic lupus erythematosus (Systemic lupus erythematosus);
Unknown to Ongoing	Indication	Lupus erythematosus (Systemic lupus erythematosus);