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	GUATEMALA		PRIVACY		Unk	Female	Unk		JAN	2025

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
Severe allergy on my face and neck [Hypersensitivity]	ANIFROLUMAB	Yes	No	Not Applicable	Related
skin was left feeling dry [Dry skin]	ANIFROLUMAB	Yes	No	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) ANIFROLUMAB (ANIFROLUMAB) Solution for injection

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

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

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

18. THERAPY DATES(from/to)
#1) 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 (Systemic lupus erythematosus)
Unknown	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 #: GT-ASTRAZENECA-202504CAM026006GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00859527A

24b. MFR CONTROL NO.
202504CAM026006GT

24c. DATE RECEIVED BY MANUFACTURER
29-APR-2025

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

DATE OF THIS REPORT
06-MAY-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 had been received from a consumer in Patient Support Program concerning a female patient born in 1968.

No medical history and concomitant products were reported.

On an unknown date, the patient started treatment with Anifrolumab (anifrolumab) 300 milligram q4w, Intravenous use, for lupus.

During 15-JAN-25, the patient experienced severe allergy on my face and neck (preferred term: Hypersensitivity). On an unknown date, the patient experienced skin was left feeling dry (preferred term: Dry skin).

The dose of Anifrolumab (anifrolumab) was not changed.

The patient recovered with sequelae from the event(s) severe allergy on my face and neck after 2 days. The outcome of the event(s) of skin was left feeling dry was unknown.

The reporter assessed the events severe allergy on my face and neck and skin was left feeling dry serious due to seriousness criteria as Medically Significant.

The reporter did not assess causality for severe allergy on my face and neck and skin was left feeling dry.

The company physician considered that there was a reasonable possibility of a causal relationship between Anifrolumab and the following event(s): severe allergy on my face and neck and skin was left feeling dry.

Company Clinical Comment: Hypersensitivity and dry skin are not listed in the company core data sheet of anifrolumab. Underlying lupus could be confounding. Due to limited information on exact circumstances leading to the events, start date of suspect drug, clinical course and treatment provided for the events, relevant medical history, concurrent conditions and concomitant medications, possible risk factors, allergic history, detailed etiological and diagnostic workup, the evaluation did not find evidence to exclude a causal relationship between the events and suspect drug.