SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		45 Years	Female	Unk	10	DEC	2024

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

(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) Ultomiris (Ravulizumab) Concentrate for solution for infusion

(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 3300 milligram, q8w	#1) Intravenous use

17. INDICATION(S) FOR USE

#1) Paroxysmal nocturnal hemoglobinuria (P

(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 10-DEC-2024 / Ongoing	#1) Unknown

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	
Unknown	Indication	

(Continued on Additional Information Page)

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-202412CAM014390CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00770342A
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24b. MFR CONTROL NO.

202412CAM014390CR

25b. NAME AND ADDRESS OF REPORTER

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER

28-APR-2025

24d. REPORT SOURCE

☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT

05-MAY-2025

25a. REPORT TYPE

☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 202412CAM014390CR

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 (age 45 years) who was enrolled in PSP-23269, Disfruto Mi Salud Biopharma is an affordability program.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Ultomiris (ravulizumab) 3300 milligram q8w, Intravenous use, on 10-DEC-2024 for paroxysmal nocturnal hemoglobinuria.

On 10-DEC-24, the patient experienced headache (preferred term: Headache). On an unknown date, the patient experienced nausea (preferred term: Nausea).

The dose of Ultomiris (ravulizumab) was not changed.

The patient recovered from the event(s) nausea on an unspecified date. At the time of reporting, the event headache was improving.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Ultomiris and the following event(s): headache and nausea.

The company physician considered that there was a reasonable possibility of a causal relationship between Ultomiris and the following event(s): headache and nausea.

Summary of follow-up information received by AstraZeneca on13-Jan-2025: All required follow-up attempts have been completed to obtain the Lot/Batch number for ALXN1210 (Ravulizumab), 2700mg which was received on an unspecified, however the Lot / Batch number was not received.

Summary of follow-up information received by AstraZeneca by the patient on 28-APR-2025: Updated the dosing details of Ultomiris from (2700 mg) to (3300 mg) with the frequency (q8w) and the study-ID from DMS (Disfruto Mi Salud) to PSP-23269.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Ultomiris (Ravulizumab) Concentrate for solution for infusion; Regimen #1	3300 milligram, q8w; Intravenous use	Paroxysmal nocturnal hemoglobinuria (Paroxysmal nocturnal haemoglobinuria)	10-DEC-2024 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Paroxysmal nocturnal haemoglobinuria (Paroxysmal nocturnal haemoglobinuria);
Unknown	Indication	Paroxysmal nocturnal hemoglobinuria (Paroxysmal nocturnal haemoglobinuria);