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	GUATEMALA		PRIVACY		79 Years	Male	Unk		DEC	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
Exaggerated fatigue [Fatigue]	Ultomiris	No	Yes	Not Applicable	Related
Exaggerated fatigue [Fatigue]	TAGRISSO	No	No	Not Related	Not Related
Could not walk [Gait disturbance]	Ultomiris	No	No	Not Applicable	Related
Could not walk [Gait disturbance]	TAGRISSO	No	No	Not Related	Not 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) Ultomiris (Ravulizumab) Concentrate for solution for infusion
#2) TAGRISSO (OSIMERTINIB) Tablet {Lot # FLWY; Exp.Dt. AUG-2027}

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1) UNK
#2) 80 milligram, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown
#2) Oral use

17. INDICATION(S) FOR USE
#1) Unknown
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) Unknown
#2) Unknown

19. THERAPY DURATION
#1) Unknown
#2) 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

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-202506CAM006044GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00887651AM

24b. MFR CONTROL NO.
202506CAM006044GT

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
09-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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Bronchitis [Bronchitis]	Ultomiris	No	No	Not Applicable	Related
Bronchitis [Bronchitis]	TAGRISSO	No	No	Not Related	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a male elderly patient (age 79 years) who was enrolled in PSP-23269, Disfruto Mi Salud Biopharma is an affordability program with the objective of give accompaniment to our patients, give more access to AZ products and increase adherence: The program has presence in 6 CAMCAR countries CR, GT, HN, PA, DO, Our portfolio includes Forxiga, Xigduo & Breztri, Benefits: - 4+1 or 30% discount in all our portfolio, - 2+1 or 33% discount for our polimedicated patients that are in 2 or more AZ cardiometabolic treatments, - Portal site with educational information, devices information, health tips, exercise routines, healthy recipes. Disfruto Mi Salud Oncology/Inmunology/Rare Diseases is a support program with the objective of improve the mental and physical patient and caregiver wellness, The program has presence in 6 CAMCAR countries CR, GT, SV, PA, DO, Our portfolio includes Imfinzi, Tagrisso, Truqap, Tezspire, Koselugo, Lynparza, Zoladex-ProZoladex, Faslodex, Calquence Fasenra, Saphnelo, Enhertu, Synagis, Ultomiris, Disfruto Mi Salud have different benefits to our patients - Starter kit, - Nurse/Navigator support, - Educational information, - Psychology support, - Nutritional advice, - Physical Therapy, - Sexology, - Dermatology, - CoPayment Program, - TALM: Affordability program for private patients under the 1+1 scheme.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib) (batch number(s) FLWY) (expiration date(s) AUG-2027) 80 milligram qd, Oral use, on an unknown date and with Ultomiris (ravulizumab) UNK, on an unknown date.

During DEC-24, the patient experienced exaggerated fatigue (preferred term: Fatigue). On 29-JAN-25, the patient experienced could not walk (preferred term: Gait disturbance) and bronchitis (preferred term: Bronchitis).

Treatment with Tagrisso (osimertinib) was temporarily Withdrawn. It is unknown if any action was taken with Ultomiris (ravulizumab).

The patient recovered with sequelae from the event(s) exaggerated fatigue on 07-JAN-2025. At the time of reporting, the event bronchitis and could not walk was ongoing.

The events were considered non-serious.

The reporter did not assess causality for bronchitis, could not walk and exaggerated fatigue.The reporter did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): bronchitis, could not walk and exaggerated fatigue.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): bronchitis, could not walk and exaggerated fatigue. The company physician considered that there was a reasonable possibility of a causal relationship between Ultomiris and the following event(s): bronchitis, could not walk and exaggerated fatigue.