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	PANAMA		PRIVACY		Unk	Female	Unk	11	JUN	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
ITCHING OF THE SKIN [Pruritus]	TAGRISSO	No	Yes	Related	Related
REDNESS OF THE SKIN [Erythema]	TAGRISSO	No	Yes	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) TAGRISSO (OSIMERTINIB) Tablet {Lot # Unknown}

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

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

17. INDICATION(S) FOR USE
#1) lung cancer (Lung cancer)

18. THERAPY DATES(from/to)
#1) 28-MAY-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	Lung cancer (Lung cancer)

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 #: PA-ASTRAZENECA-202506CAM009438PA
Study ID: PSP-23269
Case References: PA-AstraZeneca-CH-00889985A

24b. MFR CONTROL NO.
202506CAM009438PA

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

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

DATE OF THIS REPORT
16-JUN-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. The report concerning a female patient (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib) (batch number(s) Unknown) 80 milligram qd, Oral use, on 28-MAY-2025 for lung cancer.

On 11-JUN-25, the patient experienced redness of the skin (preferred term: Erythema) and itching of the skin (preferred term: Pruritus).

The dose of Tagrisso (osimertinib) was not changed.

At the time of reporting, the event itching of the skin and redness of the skin was improving.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): itching of the skin and redness of the skin.
The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): itching of the skin and redness of the skin.