CIOMS FORM

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	09	JUL	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
Nauseas [Nausea]	TAGRISSO	No	No	Related	Related
uñas agrietadas [Onychoclasis]	TAGRISSO	No	Yes	Related	Related
Dolor abdominal [Abdominal pain]	TAGRISSO	No	No	Related	Related
Lesiones de estómago (endoscopía) [Gastric mucosal lesion]	TAGRISSO	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) TAGRISSO (OSIMERTINIB) Tablet

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) 04-SEP-2024 / 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	Lung cancer (Lung neoplasm malignant)

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-202503CAM024357PA
Study ID: PSP-23269
Case References: PA-AstraZeneca-CH-00837356A

24b. MFR CONTROL NO.
202503CAM024357PA

24c. DATE RECEIVED BY MANUFACTURER
31-JUL-2025

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

DATE OF THIS REPORT
05-AUG-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 has been received from a consumer in Patient Support Program. The report concerns a female patient (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib) 80 milligram qd, Oral use, on 04-SEP-2024 for lung cancer.

On 09-JUL-25, the patient experienced dolor abdominal (preferred term: Abdominal pain) and lesiones de estómago (endoscopía) (preferred term: Gastric mucosal lesion). On an unknown date, the patient experienced nauseas (preferred term: Nausea) and uñas agrietadas (preferred term: Onychoclasis).

Treatment with Tagrisso (osimertinib) was temporarily Withdrawn.

At the time of reporting, the event uñas agrietadas was improving. At the time of reporting, the event nauseas was improving. The outcome of the event(s) of dolor abdominal and lesiones de estómago (endoscopía) was unknown.

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): dolor abdominal, lesiones de estómago (endoscopía), nauseas and uñas agrietadas.
The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): dolor abdominal, lesiones de estómago (endoscopía), nauseas and uñas agrietadas.

Summary of follow-up information received by AstraZeneca 31-Jul-2025: Event Abdominal pain, Stomach lesions (endoscopy) added. Narrative updated.