

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

|  |                                 |                  |                |      |                               |                         |                          |                    |       |             |  |
|--|---------------------------------|------------------|----------------|------|-------------------------------|-------------------------|--------------------------|--------------------|-------|-------------|--|
| 1. PATIENT INITIALS<br>(first, last)<br><b>PRIVACY</b> | 1a. COUNTRY<br><b>GUATEMALA</b> | 2. DATE OF BIRTH |                |      | 2a. AGE<br><b>63</b><br>Years | 3. SEX<br><b>Female</b> | 3a. WEIGHT<br><b>Unk</b> | 4-6 REACTION ONSET |       |             | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|  |                                 | Day              | Month          | Year |                               |                         |                          | Day                | Month | Year        |  |
|  |                                 |                  | <b>PRIVACY</b> |      |                               |                         |                          |                    |       | <b>2022</b> |  |

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 |
|---|----------|---------|--------|--------------------|-------------------|
| SUFFOCATING [Asphyxia]  | TAGRISSO | Yes     | No     | Related            | Related           |
| DIARRHEA [Diarrhoea]  | TAGRISSO | Yes     | Yes    | Related            | Related           |
| RASH [Rash]   | TAGRISSO | No      | Yes    | Related            | Related           |
| ITCHING [Pruritus]  | TAGRISSO | No      | Yes    | Related            | Related           |
| TINGLING [Paraesthesia]   | TAGRISSO | No      | No     | Related            | Related           |

(Continued on Additional Information Page)

☐ 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)<br>#1 ) TAGRISSO (OSIMERTINIB) Tablet {Lot # Unknown} |   | 20. DID REACTION ABATE AFTER STOPPING DRUG?<br><br><input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA     |
| 15. DAILY DOSE(S)<br>#1 ) 80 milligram, qd   | 16. ROUTE(S) OF ADMINISTRATION<br>#1 ) Oral use |  |
| 17. INDICATION(S) FOR USE<br>#1 ) Lung cancer (Lung neoplasm malignant)                          |   | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION?<br><br><input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA |
| 18. THERAPY DATES(from/to)<br>#1 ) 28-OCT-2022 / 2025  | 19. THERAPY DURATION<br>#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<br>Unknown to Ongoing<br>Unknown   | Type of History / Notes<br>Indication<br>Indication | Description<br>Drug prescription issue (Product prescribing issue)<br>Lung cancer (Lung neoplasm malignant) |

## IV. MANUFACTURER INFORMATION

|   |   |   |
|---|---|---|
| 24a. NAME AND ADDRESS OF MANUFACTURER<br>AstraZeneca<br>Serban Ghiorghiu<br>1 Medimmune Way<br>Gaithersburg, Maryland 20878 UNITED STATES<br>Phone: +1 301-398-0000 |   | 26. REMARKS<br>World Wide #: GT-AstraZeneca-2023A099729<br>Case References: GT-AstraZeneca-2023A099729  |
|   | 24b. MFR CONTROL NO.<br><b>2023A099729</b>  | 25b. NAME AND ADDRESS OF REPORTER<br>NAME AND ADDRESS WITHHELD.<br><br>NAME AND ADDRESS WITHHELD.<br><br>NAME AND ADDRESS WITHHELD.<br><br>NAME AND ADDRESS WITHHELD. |
| 24c. DATE RECEIVED BY MANUFACTURER<br><b>09-MAY-2025</b>  | 24d. REPORT SOURCE<br><input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE<br><input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER: |   |
| DATE OF THIS REPORT<br><b>16-MAY-2025</b>   | 25a. REPORT TYPE<br><input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1  |   |

16-May-2025 05:52

**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 |
|---|----------|---------|--------|--------------------|-------------------|
| SINCE I STARTED TAKING THE MEDICATION, I'M NOT HUNGRY. THE DOCTOR ALREADY TOLD ME TO TRY TO EAT MORE BUT I CAN'T. MY HUNGER HAS DISAPPEARED; I EAT VERY LITTLE. I START TO EAT AND THE HUNGER GOES AWAY. I HAVEN'T MANAGED TO GAIN ANY WEIGHT AND THE DOCT [Decreased appetite] | TAGRISSO | No      | No     | Related            | Related           |

Case Description: A solicited report from a non-interventional study/data collection program has been received from from a non-health professional concerning a female adult patient of Unknown ethnic origin born in 1959 (age 63 years).

No medical history was reported. No concomitant products were reported.

On 28-OCT-2022, the patient started treatment with Tagrisso (osimertinib) (batch number(s) Unknown) 80 milligram qd, Oral use, for lung cancer.

During 15-JUN-22, the patient experienced since i started taking the medication, I'm not hungry. the doctor already told me to try to eat more but i can't my hunger has disappeared; i eat very little. i start to eat and the hunger goes away. i haven't managed to gain any weight and the doct (preferred term: Decreased appetite). During 15-FEB-23, the patient experienced suffocating (preferred term: Asphyxia). On an unknown date, the patient experienced diarrhea (preferred term: Diarrhoea), tingling (preferred term: Paraesthesia), itching (preferred term: Pruritus) and rash (preferred term: Rash).

The dose of Tagrisso (osimertinib) was not changed.

At the time of reporting, the event since i started taking the medication, i'm not hungry. the doctor already told me to try to eat more but i can't. my hunger has disappeared; i eat very little. i start to eat and the hunger goes away. i haven't managed to gain any weight and the doct was ongoing. The outcome of the event(s) of diarrhea, itching, rash, suffocating and tingling was unknown.

The event of suffocating was upgraded by the company physician from non-serious to serious due to important medical event criterion.

The reporter assessed the event diarrhea as serious due to important medical event criterion.

The reporter assessed the events of itching, rash, since i started taking the medication, i'm not hungry. the doctor already told me to try to eat more but i can't. my hunger has disappeared; i eat very little. i start to eat and the hunger goes away. i haven't managed to gain any weight and the doct and tingling as non serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): diarrhea, itching, rash, since i started taking the medication, i'm not hungry. the doctor already told me to try to eat more but i can't. my hunger has disappeared; i eat very little. i start to eat and the hunger goes away. i haven't managed to gain any weight and the doct, suffocating and tingling.

The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): diarrhea, itching, rash, since i started taking the medication, i'm not hungry. the doctor already told me to try to eat more but i can't. my hunger has disappeared; i eat very little. i start to eat and the hunger goes away. i haven't managed to gain any weight and the doct, suffocating and tingling.

15-May-2025: Summary of follow up information received by AstraZeneca on 09-May-2025 from consumer via solicited source: New non serious event since i started taking the medication, i'm not hungry. the doctor already told me to try to eat more but i can't. my hunger has disappeared; i eat very little. i start to eat and the hunger goes away. i haven't managed to gain any weight and the doct added. start date of suspect updated and end date added. Narrative updated

Company Clinical Comment: Asphyxia is not listed in company core data sheet of Osimertinib. Underlying lung cancer could be confounding factor for the event. Due to limited information on circumstances leading to event, treatment given, outcome of the event, recent status of the underlying malignancy, concomitant medications, concomitant conditions, risk factors, medical history, detailed etiological and diagnostic work up including baseline reports if any, the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between the event and the suspect drug.