

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 63 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			PRIVACY						MAR	2024	

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
Patient presents diarrhea [Diarrhoea]	TAGRISSO	Yes	Yes	Not Related	Related
Patient presents diarrhea [Diarrhoea]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
vomiting [Vomiting]	TAGRISSO	Yes	No	Not Applicable	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) #1) TAGRISSO (OSIMERTINIB) Tablet #2) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 80 milligram, qd #2) UNK	16. ROUTE(S) OF ADMINISTRATION #1) Oral use #2) Unknown	
17. INDICATION(S) FOR USE #1) Lung cancer (Lung neoplasm malignant) #2) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) Ongoing #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) #1) Salbutamol (Salbutamol sulfate) ; Unknown	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)	
From/To Dates Unknown to Ongoing 2020 to Unknown	Type of History / Notes Indication Historical Condition Patient indicates he developed pneumonia or COVID-19 in 2020. (Exact dates not provided)
Description Lung cancer (Lung cancer) Pneumonia (Pneumonia)	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgheiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202501CAM009934CR Study ID: DMS (Disfruto Mi Salud) Case References: CR-AstraZeneca-CH-00784770AM
	24b. MFR CONTROL NO. 202501CAM009934CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 25-APR-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 30-APR-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

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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
vomiting [Vomiting]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
tachycardia [Tachycardia]	TAGRISSE	Yes	No	Not Applicable	Related
tachycardia [Tachycardia]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
arm pain [Pain in extremity]	TAGRISSE	Yes	No	Not Applicable	Not Related
arm pain [Pain in extremity]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
stomach pain [Abdominal pain upper]	TAGRISSE	Yes	No	Not Applicable	Related
stomach pain [Abdominal pain upper]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
metastasis in right lung [Metastases to lung]	TAGRISSE	Yes	No	Not Applicable	Not Related
metastasis in right lung [Metastases to lung]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
breast cancer [Breast cancer]	TAGRISSE	Yes	No	Not Applicable	Not Related
breast cancer [Breast cancer]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
lung infections [Pneumonia]	TAGRISSE	Yes	No	Not Applicable	Not Related
lung infections [Pneumonia]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
Patient indicates that he has stage 3 kidney problems due to taking many medications. [Renal disorder]	TAGRISSE	Yes	No	Not Related	Not Related
Patient indicates that he has stage 3 kidney problems due to taking many medications. [Renal disorder]	DAPAGLIFLOZIN	Yes	No	Not Applicable	Not Applicable
feel unwell [Malaise]	TAGRISSE	No	No	Not Applicable	Not Related
feel unwell [Malaise]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient indicates that he hears less in the right ear [Hypoacusis]	TAGRISSE	No	No	Not Related	Related
Patient indicates that he hears less in the right ear [Hypoacusis]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient indicates that his vision problems have worsened to the point where he currently sees blurry [Vision blurred]	TAGRISSE	No	No	Not Related	Related
Patient indicates that his vision problems have worsened to the point where he currently sees blurry [Vision blurred]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient indicates that he has lost 50% of his sense of smell [Anosmia]	TAGRISSE	No	No	Not Related	Related
Patient indicates that he has lost 50% of his sense of smell [Anosmia]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient has memory problems [Memory impairment]	TAGRISSE	No	No	Not Related	Related
Patient has memory problems [Memory impairment]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient presents shortness of breath [Dyspnoea]	TAGRISSE	No	No	Not Related	Not Related
Patient presents shortness of breath [Dyspnoea]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient presents fatigue [Fatigue]	TAGRISSE	No	No	Not Related	Related
Patient presents fatigue [Fatigue]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Hives [Urticaria]	TAGRISSE	No	Yes	Not Related	Related
Hives [Urticaria]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient presents pain in lungs [Pulmonary pain]	TAGRISSE	No	No	Not Applicable	Not Related
Patient presents pain in lungs [Pulmonary pain]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient presents stress [Stress]	TAGRISSE	No	No	Not Related	Related
Patient presents stress [Stress]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Patient presents cough with phlegm [Productive cough]	TAGRISSE	No	No	Not Related	Not Related
Patient presents cough with phlegm [Productive cough]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Illness [Illness]	TAGRISSE	No	No	Not Applicable	Not Related
Illness [Illness]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
BLEEDING [Haemorrhage]	TAGRISSE	No	No	Not Applicable	Not Related
BLEEDING [Haemorrhage]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
had a fall a week ago [Fall]	TAGRISSE	No	No	Not Applicable	Not Related
had a fall a week ago [Fall]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Stronger dizziness [Dizziness]	TAGRISSE	No	No	Not Applicable	Related
Stronger dizziness [Dizziness]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Skin rash with burning [Skin burning sensation]	TAGRISSE	No	No	Not Applicable	Related
Skin rash with burning [Skin burning sensation]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable
Itchy skin rash [Pruritus]	TAGRISSE	No	Yes	Not Applicable	Related
Itchy skin rash [Pruritus]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Applicable

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female adult patient born in 1961 (age 63 years).

The patient's past and current medical history included covid-19 (started 2020), pneumonia (started 2020), loss of hearing (ongoing) and loss of smell (dates not reported). Concomitant medication included Salbutamol.

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

On an unknown date, the patient started treatment with Dapagliflozin (dapagliflozin) UNK, and with Tagrisso (osimertinib) 80 milligram qd, Oral use, for lung cancer.

During Mar-24, the patient experienced lung infections (preferred term: Pneumonia). On 29-Nov-24, the patient experienced feel unwell (preferred term: Malaise), arm pain (preferred term: Pain in extremity), stomach pain (preferred term: Abdominal pain upper), tachycardia (preferred term: Tachycardia), vomiting (preferred term: Vomiting) and patient presents diarrhea (preferred term: Diarrhoea). On 17-Feb-25, the patient experienced stronger dizziness (preferred term: Dizziness) and had a fall a week ago (preferred term: Fall). On 25-Apr-25, the patient experienced skin rash with burning (preferred term: Skin burning sensation) and itchy skin rash (preferred term: Pruritus). On an unknown date, the patient experienced illness (preferred term: Illness), patient presents cough with phlegm (preferred term: Productive cough), breast cancer (preferred term: Breast cancer), metastasis in right lung (preferred term: Metastases to lung), patient presents stress (preferred term: Stress), patient presents pain in lungs (preferred term: Pulmonary pain), patient indicates that he has stage 3 kidney problems due to taking many medications. (preferred term: Renal disorder), hives (preferred term: Urticaria), patient presents fatigue (preferred term: Fatigue), patient presents shortness of breath (preferred term: Dyspnoea), patient has memory problems (preferred term: Memory impairment), patient indicates that he hears less in the right ear (preferred term: Hypoacusis), patient indicates that he has lost 50% of his sense of smell (preferred term: Anosmia), patient indicates that his vision problems have worsened to the point where he currently sees blurry (preferred term: Vision blurred) and bleeding (preferred term: Haemorrhage).

The dose of Tagrisso was not changed.

The outcome of the events of arm pain, bleeding, breast cancer, feel unwell, hives, illness, lung infections, metastasis in right lung, patient has memory problems, patient indicates that he has lost 50% of his sense of smell, patient indicates that he has stage 3 kidney problems due to taking many medications., patient indicates that he hears less in the right ear, patient indicates that his vision problems have worsened to the point where he currently sees blurry, patient presents cough with phlegm, patient presents diarrhea, patient presents fatigue, patient presents pain in lungs, patient presents shortness of breath, patient presents stress, stomach pain, tachycardia and vomiting was unknown. At the time of reporting, the event had a fall a week ago, itchy skin rash, skin rash with burning and stronger dizziness was ongoing.

The reporter assessed the events of patient presents diarrhea, stomach pain, arm pain, tachycardia and vomiting as serious due to hospitalized criteria.

The reporter assessed the events of lung infections, breast cancer, metastasis in right lung and patient indicates that he has stage 3 kidney problems due to taking many medications as serious due to medically significant criterion.

The reporter assessed the events of bleeding, feel unwell, hives, illness, patient has memory problems, patient indicates that he has lost 50% of his sense of smell, patient indicates that he hears less in the right ear, patient indicates that his vision problems have worsened to the point where he currently sees blurry, patient presents cough with phlegm, patient presents fatigue, patient presents pain in lungs, patient presents shortness of breath and patient presents stress as non-serious.

The company physician assessed the events of itchy skin rash, had a fall a week ago, skin rash with burning and stronger dizziness as non-serious.

The reporter did not assess causality for arm pain, bleeding, breast cancer, feel unwell, had a fall a week ago, hives, illness, itchy skin rash, lung infections, metastasis in right lung, patient has memory problems, patient indicates that he has lost 50% of his sense of smell, patient indicates that he has stage 3 kidney problems due to taking many medications., patient indicates that he hears less in the right ear, patient indicates that his vision problems have worsened to the point where he currently sees blurry, patient presents cough with phlegm, patient presents diarrhea, patient presents fatigue, patient presents pain in lungs, patient presents shortness of breath, patient presents stress, skin rash with burning, stomach pain, stronger dizziness, tachycardia and vomiting. The reporter did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): hives, patient has memory problems, patient indicates that he has lost 50% of his sense of smell, patient indicates that he has stage 3 kidney problems due to taking many medications., patient indicates that he hears less in the right ear, patient indicates that his vision problems have worsened to the point where he currently sees blurry, patient presents cough with phlegm, patient presents diarrhea, patient presents fatigue, patient presents shortness of breath and patient presents stress.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): arm pain, bleeding, breast cancer, feel unwell, had a fall a week ago, illness, lung infections, metastasis in right lung, patient indicates that he has stage 3 kidney problems due to taking many medications., patient presents cough with phlegm, patient presents pain in lungs and patient presents shortness of breath. The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): hives, itchy skin rash, patient has memory problems, patient indicates that he has lost 50% of his sense of smell, patient indicates that he hears less in the right ear, patient indicates that his vision problems have worsened to the point where he currently sees blurry, patient presents diarrhea, patient presents fatigue, patient presents stress, skin rash with burning, stomach pain, stronger dizziness, tachycardia and vomiting.

Laboratory values are available.

Summary of follow-up information received by AstraZeneca on 18-Mar-2025 from consumer via solicited source: Non-serious events stronger dizziness and had a fall a week ago added. Consent to follow-up with reporter updated as no. Suppress automated follow-up updated as yes. Medical history updated. Narrative updated.

Corrected report on 25-Mar-2025: MAH causality updated from related to not related for events illness, bleeding, vomiting, feeling unwell, stomach ache, tachycardia, pain in extremity. Patient indicates that he has stage 3 kidney problems due to taking many medications recoded to kidney disorder. Narrative amended.

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Summary of follow-up information received by AstraZeneca on 25-Apr-2025 from consumer via solicited source: New non-serious adverse events Skin burning sensation and Pruritus added. Narrative updated. Corrected report on 30-Apr-2025: All related information to product dapagliflozin was corrected. Narrative updated.

Company Clinical Comment: Vomiting, tachycardia and abdominal pain upper are not listed in the company core data sheet of Osimertinib and Dapagliflozin. Underlying malignancy may be confounding. Due to limited information on start date of the suspect drugs, outcome of the events, circumstances surrounding the events, aetiological and diagnostic workup, concurrent diseases, other concomitant medications, risk factors, the evaluation did not find evidence to exclude a causal relationship between the events and the suspect drugs.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Computerised tomogram unknown		
2		Immunology test unknown		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2020 to Unknown	Historical Condition	COVID-19 (COVID-19); Patient indicates he developed pneumonia or COVID-19 in 2020. (Exact dates not provided)
Unknown to Ongoing	Current Condition	Hearing loss (Deafness); Patient reports loss of hearing and smell; hearing aids were recently sent to him.
Unknown	Historical Condition	Loss of smell (Anosmia); Patient reports loss of hearing and smell; hearing aids were recently sent to him.