

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 48 Years	3. SEX Female	3a. WEIGHT 60.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			PRIVACY				20	JUL	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
Fatigue/Tiredness/ Fatiga [Fatigue]	ENHERTU	No	Yes	Related	Related
Nausea [Nausea]	ENHERTU	No	Yes	Related	Related
Loss of appetite [Decreased appetite]	ENHERTU	No	Yes	Related	Related
Muscle pain [Myalgia]	ENHERTU	No	No	Related	Related
Headache [Headache]	ENHERTU	No	Yes	Related	Related
Back pain [Back pain]	ENHERTU	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) #1) ENHERTU (TRASTUZUMAB DERUXTECAN) Powder for solution for infusion		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) 5.4 milligram/kilogram, q3w	16. ROUTE(S) OF ADMINISTRATION #1) Intravenous use	
17. INDICATION(S) FOR USE #1) Breast cancer (Breast cancer)		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) 17-JUL-2024 / Ongoing	19. THERAPY DURATION #1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) Omeprazole (Omeprazole magnesium) ; Unknown

#2) Antihistamines (Antihistamines) ; Unknown

#3) Other antiemetics (Other antiemetics) ; Unknown

#4) Gabapentin (Gabapentin) ; Unknown

#5) Carvediol (Carvedilol) ; Unknown

#6) Metformin (Metformin hydrochloride) ; Unknown

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	Breast cancer (Breast cancer)
Unknown	Historical Condition	Diabetes mellitus (Diabetes mellitus)

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 #: CR-ASTRAZENECA-202412CAM009024CR Study ID: DMS Case References: CR-AstraZeneca-CH-00766538A
	24b. MFR CONTROL NO. 202412CAM009024CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 05-JUN-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 11-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	

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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
Constipation [Constipation]	ENHERTU	No	Yes	Related	Related
Diarrhea [Diarrhoea]	ENHERTU	No	Yes	Related	Related
Heartburn [Dyspepsia]	ENHERTU	No	Yes	Related	Related
Discomfort, like I just want to stay in bed and wait for that feeling to pass. [Dissociation]	ENHERTU	No	No	Related	Related
Anxiety [Anxiety]	ENHERTU	No	No	Related	Related
restlessness [Restlessness]	ENHERTU	No	No	Related	Related
Cough [Cough]	ENHERTU	No	Yes	Related	Related
Platelets in 140000 [Platelet count decreased]	ENHERTU	No	Yes	Related	Related
Lung metastasis [Metastases to lung]	ENHERTU	Yes	No	Related	Not Related
Hair loss [Alopecia]	ENHERTU	No	Yes	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program, concerning a female adult patient born in 1975 (age 48 years, height 148 cm, weight 60 kg).

The patient's past and current medical history included diabetes mellitus (dates not reported), fibromyalgia (dates not reported) and hypertension (dates not reported). Concomitant medication included Antihistamines, Omeprazole, Other Antiemetics, Metformin, Gabapentin and Carvediol.

On 17-Jul-2024, the patient started treatment with Enhertu (trastuzumab deruxtecan) 5.4 milligram/kilogram q3w, Intravenous use, for breast cancer.

On 20-Jul-24, the patient experienced muscle pain (preferred term: Myalgia), loss of appetite (preferred term: Decreased appetite), nausea (preferred term: Nausea), fatigue/tiredness/ fatiga (preferred term: Fatigue), heartburn (preferred term: Dyspepsia), diarrhea (preferred term: Diarrhoea), constipation (preferred term: Constipation), back pain (preferred term: Back pain) and headache (preferred term: Headache). On an unknown date, the patient experienced discomfort, like i just want to stay in bed and wait for that feeling to pass. (preferred term: Dissociation), restlessness (preferred term: Restlessness), anxiety (preferred term: Anxiety), hair loss (preferred term: Alopecia), lung metastasis (preferred term: Metastases to lung), platelets in 140000 (preferred term: Platelet count decreased) and cough (preferred term: Cough).

The dose of Enhertu was not changed.

The patient recovered from the events of diarrhea and heartburn on an unspecified date. At the time of reporting, the event anxiety, back pain, constipation, cough, discomfort, like i just want to stay in bed and wait for that feeling to pass., fatigue/tiredness/ fatiga, lung metastasis, muscle pain and restlessness was ongoing. The outcome of the events of hair loss and platelets in 140000 was unknown. At the time of reporting, the event headache, loss of appetite and nausea was improving.

The event of lung metastasis added as serious due to medically significant.

The following events were considered non-serious: anxiety, back pain, constipation, cough, diarrhea, discomfort, like i just want to stay in bed and wait for that feeling to pass., fatigue/tiredness/ fatiga, hair loss, headache, heartburn, loss of appetite, muscle pain, nausea, platelets in 140000 and restlessness.

The reporter considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): anxiety, back pain, constipation, cough, diarrhea, discomfort, like i just want to stay in bed and wait for that feeling to pass., fatigue/ tiredness/ fatiga, hair loss, headache, heartburn, loss of appetite, lung metastasis, muscle pain, nausea, platelets in 140000 and restlessness.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): lung metastasis. The company physician considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): anxiety, back pain, constipation, cough, diarrhea, discomfort, like i just want to stay in bed and wait for that feeling to pass., fatigue/tiredness/ fatiga, hair loss, headache, heartburn, loss of appetite, muscle pain, nausea, platelets in 140000 and restlessness.

Laboratory values are available.

Summary of follow-up information received by AstraZeneca/MedImmune on 18-Dec-2024 from Marketing company: New concomitants were added. Patient History Updated. Patient tab updated. Narrative updated. Follow up summary updated.

Summary of follow-up information received by AstraZeneca/MedImmune on 18-Dec-2024 from Marketing company: No new information was added.

Summary of follow up information received by AstraZeneca/Medimmune on 06-Mar-2025 from consumer via Patient Support Program source: New non serious events anxiety and restlessness was added. Narrative was updated.

Summary of follow-up information received by AstraZeneca on 06-Jun-2025 from pharmacist via email: New non-serious events, Cough, Platelet count decreased, and Alopecia added. New serious event, Metastases to lung added. Addition of reporter. Narrative

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ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued
updated.

Company Clinical Comment: Metastases to lung is not listed event in the core data sheet for trastuzumab deruxtecan. underlying breast cancer could provide alternative explanation for occurrence of the event.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Platelet count decreased		

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Hypertension (Hypertension);
Unknown	Historical Condition	Fibromyalgia (Fibromyalgia);