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	COSTA RICA		PRIVACY		Unk	Female	Unk			2025

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
Mediastinum cancer/cancer in the mediastinum [Mediastinum neoplasm]	ENHERTU	Yes	No	Not Applicable	Not Related
Disease progression [Malignant neoplasm progression]	ENHERTU	Yes	No	Not Applicable	Not Related
Nausea [Nausea]	ENHERTU	No	Yes	Related	Related
He couldn't move [Hypokinesia]	ENHERTU	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) ENHERTU (TRASTUZUMAB DERUXTECAN) Powder for solution for infusion {Lot # Unknown}

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ 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? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) 18-OCT-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)

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)

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-202412CAM015404CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00770942A

24b. MFR CONTROL NO.
202412CAM015404CR

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
06-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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
Headache/lot of pain in my head [Headache]	ENHERTU	No	Yes	Related	Related
Body ache/lot of pain in my body [Pain]	ENHERTU	No	No	Related	Related
Hoarseness [Dysphonia]	ENHERTU	No	No	Not Applicable	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program, concerning a female patient born in 1985.

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

On 18-OCT-2024, the patient started treatment with Enhertu (trastuzumab deruxtecan) (batch number(s) Unknown) 5.4 milligram/kilogram q3w, Intravenous use, for breast cancer.

During 15-JUN-25, the patient experienced he couldn't move (preferred term: Hypokinesia), body ache/lot of pain in my body (preferred term: Pain) and headache/lot of pain in my head (preferred term: Headache). On an unknown date, the patient experienced nausea (preferred term: Nausea), mediastinum cancer/cancer in the mediastinum (preferred term: Mediastinum neoplasm), disease progression (preferred term: Malignant neoplasm progression) and hoarseness (preferred term: Dysphonia).

It is unknown if any action was taken with Enhertu.

The outcome of the event(s) of disease progression, hoarseness and mediastinum cancer/cancer in the mediastinum was unknown. At the time of reporting, the event body ache/lot of pain in my body, he couldn't move and headache/lot of pain in my head was improving. At the time of reporting, the event nausea was ongoing.

The following event(s) were considered serious due to medically significant:mediastinum cancer/cancer in the mediastinum and disease progression.

The following events were considered non-serious:body ache/lot of pain in my body, he couldn't move, headache/lot of pain in my head, hoarseness and nausea.

The reporter did not assess causality for disease progression, hoarseness and mediastinum cancer/cancer in the mediastinum.The reporter considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): body ache/lot of pain in my body, he couldn't move, headache/lot of pain in my head and nausea.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): disease progression and mediastinum cancer/cancer in the mediastinum. The company physician considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): body ache/lot of pain in my body, he couldn't move, headache/lot of pain in my head, hoarseness and nausea.

Summary of follow-up information received by AstraZeneca on 31-JUL-2025: New serious event Mediastinum cancer/cancer in the mediastinum and Disease progression was added. New non-serious event He couldn't move, Headache/lot of pain in my head, Body ache/lot of pain in my body and Hoarseness was added. Suspect drug start date and action taken was updated. Study details was updated. Narrative updated.