SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		55 Years	Female	Unk	20	JUN	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
Lack of appetite [Decreased appetite]	ENHERTU	No	Yes	Related	Related
Headache [Headache]	ENHERTU	No	Yes	Related	Related
Nausea [Nausea]	ENHERTU	No	Yes	Related	Related
Weakness [Asthenia]	ENHERTU	No	Yes	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}

15. DAILY DOSE(S)
#1) 100 milligram, q3w

16. ROUTE(S) OF ADMINISTRATION
#1) Intravenous use

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

18. THERAPY DATES(from/to)
#1) MAY-2025 / 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	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-202507CAM019917CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00917259A

24b. MFR CONTROL NO.
202507CAM019917CR

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

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

DATE OF THIS REPORT
28-JUL-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 non-health professional in Patient Support Program. The report concerns a female adult patient born in 1970 (age 55 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Enhertu (trastuzumab deruxtecan) (batch number(s) Unknown) 100 milligram q3w, Intravenous use, during MAY-2025 for breast cancer.

On 20-JUN-25, the patient experienced lack of appetite (preferred term: Decreased appetite), weakness (preferred term: Asthenia), nausea (preferred term: Nausea) and headache (preferred term: Headache).

The dose of Enhertu (trastuzumab deruxtecan) was not changed.

At the time of reporting, the event headache, lack of appetite, nausea and weakness was ongoing.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): headache, lack of appetite, nausea and weakness.
The company physician considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): headache, lack of appetite, nausea and weakness.