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		Unk	

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
Disease progression [Malignant neoplasm progression]	TRASTUZUMAB DERUXTECAN	Yes	No	Not Applicable	Not Related
Fatigue [Fatigue]	TRASTUZUMAB DERUXTECAN	No	Yes	Not Applicable	Not Related
Mobility issues [Mobility decreased]	TRASTUZUMAB DERUXTECAN	No	No	Not Applicable	Not 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) TRASTUZUMAB DERUXTECAN (TRASTUZUMAB DERUXTECAN) Powder for solution for infusion

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)

18. THERAPY DATES(from/to)
#1) 01-MAY-2024 / Ongoing

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-202504CAM027065CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00860294A

24b. MFR CONTROL NO.
202504CAM027065CR

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
06-MAY-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 consumer in Patient Support Program concerning a female adult patient born in 1983.

No medical history and concomitant products were reported.

On 01-May-2024, the patient started treatment with Trastuzumab Deruxtecan 5.4 milligram/kilogram every 3weeks, Intravenous use, for breast cancer.

On an unknown date, the patient experienced disease progression (preferred term: Malignant neoplasm progression), mobility issues (preferred term: Mobility decreased) and fatigue (preferred term: Fatigue).

The dose of Trastuzumab Deruxtecan was not changed.

The outcome of the events of mobility issues was unknown. At the time of reporting, the event disease progression and fatigue was ongoing.

The reporter assessed event of disease progression as serious due to seriousness important medical event.

The following events were considered non-serious: fatigue and mobility issues.

The reporter did not assess causality for disease progression, fatigue and mobility issues.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Trastuzumab Deruxtecan and the following events: disease progression, fatigue and mobility issues.