CIOMS FORM

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
Herpes zoster [Herpes zoster]	ENHERTU	Yes	No	Related	Related
Disease progression [Malignant neoplasm progression]	ENHERTU	Yes	No	Related	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) ENHERTU (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) 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-202412CAM015725CR
Study ID: DMS
Case References: CR-AstraZeneca-CH-00771244A

24b. MFR CONTROL NO.
202412CAM015725CR

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

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

DATE OF THIS REPORT
05-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
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 about a female patient born in 1955.

No medical history and concomitant products were reported.

On an unknown date ,The patient started treatment with Enhertu (trastuzumab deruxtecan) 5.4 milligram/kilogram q3w, Intravenous use, for breast cancer.

On an unknown date, the patient experienced herpes zoster (preferred term: Herpes zoster) and disease progression (preferred term: Malignant neoplasm progression).

At the time of reporting, the event herpes zoster was improving. At the time of reporting, the event disease progression was ongoing.

The events were considered serious (Medically Significant).

The reporter considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): disease progression and herpes zoster.
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. The company physician considered that there was a reasonable possibility of a causal relationship between Enhertu and the following event(s): herpes zoster.

Summary of follow up information received by AstraZeneca on 28-Apr-2025 from a Consumer via patient support program: New event Disease progression was added. Action taken was updated. Reporter tab updated. Narrative amended.

Company Clinical Comment: Herpes zoster and Malignant neoplasm progression are not listed in the core data sheet of Trastuzumab deruxtecan. Underlying Breast cancer which is a typically progressive disease could possibly provide alternative explanation for the event. Due to limited information on underlying comorbidities, past medical history and concomitant medications, complete etiologic and diagnostic workup the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between Event Herpes zoster and suspect drug.