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
Neutropenia [Neutropenia]	TRASTUZUMAB DERUXTECAN	Yes	Yes	Related	Related
Darkening of the skin (legs) [Skin hyperpigmentation]	TRASTUZUMAB DERUXTECAN	No	No	Related	Related
Cracked skin (legs) [Xerosis]	TRASTUZUMAB DERUXTECAN	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) 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) 18-OCT-2024 / 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-202412CAM015770CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00771257A

24b. MFR CONTROL NO.
202412CAM015770CR

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: 2

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202412CAM015770CR

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
Itchy skin patches [Pruritus]	TRASTUZUMAB DERUXTECAN	No	Yes	Related	Related
Medication wasn't working (lack of efficacy) [Drug ineffective]	TRASTUZUMAB DERUXTECAN	No	No	Related	Not Applicable

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female patient born in 1978.

No medical history and no concomitant products were reported.

On 18-Oct-2024, the patient started treatment with Trastuzumab Deruxtecan (trastuzumab deruxtecan) q3w 5.4 milligram/kilogram, q3w, Intravenous use, for breast cancer.

On an unknown date, the patient experienced neutropenia (preferred term: Neutropenia), picazón en manchas de la piel (preferred term: Pruritus), agrietamiento de la piel (piernas) (preferred term: Xerosis) and oscurecimiento de la piel (piernas) (preferred term: Skin hyperpigmentation).
The report described lack of effect for Trastuzumab Deruxtecan. The reported term was "medication wasn't working (lack of efficacy)" (preferred term: Drug ineffective).
On an unknown date, the treatment with Trastuzumab Deruxtecan was withdrawn.

At the time of reporting, the event agrietamiento de la piel (piernas), neutropenia and oscurecimiento de la piel (piernas) was improving. At the time of reporting, the event picazón en manchas de la piel was ongoing. The outcome of the event(s) of medication wasn't working (lack of efficacy) was unknown.

The Reporter assessed the event neutropenia to be serious due to seriousness criteria of important medically event.

The following events agrietamiento de la piel (piernas), medication wasn't working (lack of efficacy), oscurecimiento de la piel (piernas) and picazón en manchas de la piel were considered as non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Trastuzumab Deruxtecan and the following event(s): agrietamiento de la piel (piernas), medication wasn't working (lack of efficacy), neutropenia, oscurecimiento de la piel (piernas) and picazón en manchas de la piel.
The company physician considered that there was a reasonable possibility of a causal relationship between Trastuzumab Deruxtecan and the following event(s): agrietamiento de la piel (piernas), neutropenia, oscurecimiento de la piel (piernas) and picazón en manchas de la piel.

Summary of follow-up information received by AstraZeneca on 07-Mar-2025 from reporter via solicited source: New adverse events "Darkening of the skin", "Cracking of the skin" & "Pruritus" added; Suspect's drug action taken provided; Suspect's drug start date provided. Narrative updated.

Summary of follow up information received by AstraZeneca/Medimmune on 30-Apr-2025 from consumer via solicited report: The study Id was updated to PSP-23269. Reporter consent was updated from yes to no. Suspect drug was recoded to study configuration, action taken was updated to withdrawn. New event “medication wasn't working (lack of efficacy)” was added. Narrative updated.