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	GUATEMALA		PRIVACY		68 Years	Female	Unk	05	APR	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
Patient has low hemoglobin levels [Haemoglobin decreased]	IMFINZI	Yes	No	Not Applicable	Related
Patient has had body pain for 1 month (no exact dates indicated) [Pain]	IMFINZI	No	No	Not Applicable	Related
Patient has low sodium levels [Blood sodium decreased]	IMFINZI	No	No	Not Applicable	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) IMFINZI (DURVALUMAB) Infusion {Lot # Unknown}

15. DAILY DOSE(S)
#1) Unknown

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) (Not Coded)

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	Historical Condition	Neuropathy (Neuropathy peripheral)
Unknown	Historical Condition	Leg pain (Pain in extremity)

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 #: GT-ASTRAZENECA-202504CAM018881GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00854293A

24b. MFR CONTROL NO.
202504CAM018881GT

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

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

DATE OF THIS REPORT
29-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202504CAM018881GT

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
Patient has high potassium levels [Blood potassium increased]	IMFINZI	No	No	Not Applicable	Related
Patient suffers from sugar, but no further information is provided [Blood glucose abnormal]	IMFINZI	No	No	Not Applicable	Related

Case Description: A solicited report has been received from a other health professional in Patient Support Program concerning a female elderly patient (age 68 years).

The patient's past and current medical history included leg pain (dates not reported) and neuropathy (dates not reported).

No concomitant products were reported.

The patient started treatment with Imfinzi (durvalumab) (batch number(s) Unknown), on an unknown date.

On 05-Apr-25, the patient experienced patient has low sodium levels (preferred term: Blood sodium decreased), patient has low hemoglobin levels (preferred term: Haemoglobin decreased) and patient has high potassium levels (preferred term: Blood potassium increased). On an unknown date, the patient experienced patient has had body pain for 1 month (no exact dates indicated) (preferred term: Pain) and patient suffers from sugar, but no further information is provided (preferred term: Blood glucose abnormal).

It was unknown if any action was taken with Imfinzi.

The outcome of the event(s) of patient has had body pain for 1 month (no exact dates indicated), patient has high potassium levels, patient has low hemoglobin levels, patient has low sodium levels and patient suffers from sugar, but no further information is provided was unknown.

The company physician assessed the following event to be serious due to medically significant criterion: patient has low hemoglobin levels.

The reporter assessed the following events to be non-serious: patient has had body pain for 1 month (no exact dates indicated), patient has high potassium levels, patient has low sodium levels and patient suffers from sugar, but no further information is provided.

The company physician considered that there was a reasonable possibility of a causal relationship between Imfinzi and the following event(s): patient has had body pain for 1 month (no exact dates indicated), patient has high potassium levels, patient has low hemoglobin levels, patient has low sodium levels and patient suffers from sugar, but no further information is provided.

Laboratory values are available.

Company Clinical Comment: Haemoglobin decreased is not listed event in the company core data sheet of durvalumab. Due to limited information circumstances leading to the event, indication, start date and action taken of suspect drug, outcome of the event, clinical course of the event, relevant medical history, possible risk factors, concurrent conditions and concomitant medications, detailed etiological and diagnostic workup, the evaluation did not find evidence to exclude a causal relationship between the event and suspect drug.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose abnormal		
2		Blood potassium Patient has high potassium levels		
3		Blood sodium Patient has low sodium levels		
4		Haemoglobin Patient has low hemoglobin levels		