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	GUATEMALA		PRIVACY		73 Years	Male	Unk	03	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
Nausea [Nausea]	DURVALUMAB	Yes	No	Not Applicable	Related
Diarrhea [Diarrhoea]	DURVALUMAB	Yes	No	Not Applicable	Related
Patient was no longer eating [Decreased appetite]	DURVALUMAB	Yes	No	Not Applicable	Related
Patient did not get up [Decreased activity]	DURVALUMAB	Yes	No	Not Applicable	Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 05-JUN-2025
- ☐ 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) DURVALUMAB (DURVALUMAB) Infusion
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 1500 milligram, q4w

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

17. INDICATION(S) FOR USE
#1) Biliary tract cancer (BTC) (Bile duct cancer)
(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

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

19. THERAPY DURATION
#1) Unknown

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	Bile duct cancer (Bile duct cancer)
Unknown to Ongoing	Indication	Hepatic cancer (Hepatic 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 #: GT-ASTRAZENECA-202506CAM005781GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00887406A

24b. MFR CONTROL NO.
202506CAM005781GT

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

24c. DATE RECEIVED BY MANUFACTURER
18-JUN-2025

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

DATE OF THIS REPORT
20-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 202506CAM005781GT

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
ON WEDNESDAY HE GOT WORSE [Condition aggravated]	DURVALUMAB	Yes	No	Not Applicable	Related
Medication did not work (lack of efficacy) [Drug ineffective]	DURVALUMAB	Yes	No	Related	Related
Patient died of liver cancer [Death]	DURVALUMAB	Yes	No	Not Applicable	Related

Case Description: A solicited report had been received from a non-health professional in Patient Support Program concerning a male elderly patient born in 1952 (age 73 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Durvalumab (durvalumab) 1500 milligram q4w, Intravenous use, during FEB-2024 for biliary tract cancer (btc) and liver cancer.

On 03-Jun-2025, the patient experienced diarrhea (preferred term: Diarrhoea), nausea (preferred term: Nausea), on wednesday he got worse (preferred term: Condition aggravated), patient did not get up (preferred term: Decreased activity) and patient was no longer eating (preferred term: Decreased appetite). On an unknown date, the patient experienced medication did not work (lack of efficacy) (preferred term: Drug ineffective).

The report described lack of effect for Durvalumab. The reported term was medication did not work (lack of efficacy)(preferred term: Drug ineffective).

The dose of Durvalumab (durvalumab) was not changed.

On 05-Jun-2025,the patient died from the event diarrhea, medication did not work (lack of efficacy), nausea, on wednesday he got worse, patient did not get up and patient was no longer eating on 05-JUN-2025. The patient died (preferred term: Death).

An autopsy was not performed. The cause of death was hepatic cancer.

The reporter assessed the events to be serious due to seriousness criteria of Death.

The reporter did not assess causality for diarrhea, nausea, on wednesday he got worse, patient did not get up, patient died of liver cancer and patient was no longer eating.The reporter considered that there was a reasonable possibility of a causal relationship between Durvalumab and the following event(s): medication did not work (lack of efficacy).
The company physician considered that there was a reasonable possibility of a causal relationship between Durvalumab and the following event(s): diarrhea, medication did not work (lack of efficacy), nausea, on wednesday he got worse, patient did not get up, patient died of liver cancer and patient was no longer eating.

Summary of follow up information received by AstraZeneca on 18-Jun-2025 from physician via Spontaneous: Event dirrhoea was added. Narrative updated.

Company Clinical Comment: Fatal events of Nausea, Decreased appetite, Decreased activity and Condition aggravated are not listed in the company core data sheet of Durvalumab. Diarrhoea is listed adverse event in the company core data sheet of Durvalumab, however as the serious adverse event was reported with seriousness criteria of death, the event is considered unlisted. Elderly age of the patient could be a possible risk factor, underlying biliary tract cancer could be contributory factor. Due to limited information on exact circumstances leading to the events, other possible risk factors, concurrent diseases and concomitant medications, baseline health condition before start of the suspect drug and recent status of the underlying malignancy, past medical history, detailed aetiological and diagnostic workup, the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between the fatal events and the suspect drug.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) DURVALUMAB (DURVALUMAB) Infusion; Regimen #1	1500 milligram, q4w; Intravenous use	Biliary tract cancer (BTC) (Bile duct cancer) Liver cancer (Hepatic cancer)	FEB-2024 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Indication	Biliary carcinoma (Bile duct cancer);