CIOMS FORM

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

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)

18. THERAPY DATES(from/to)
#1) FEB-2024 / 05-JUN-2025

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	Bile duct cancer (Bile duct cancer)
Unknown	Indication	Biliary carcinoma (Bile duct 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

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

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

DATE OF THIS REPORT
10-JUN-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

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

Case Description: A solicited report has been received from a consumer 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.

During Feb-2024, the patient started treatment with Durvalumab 1500 milligram q4w, Intravenous use for biliary tract cancer (btc).

On 03-Jun-25, 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).

The last dose of DURVALUMAB prior to onset was taken on 05-Jun-25.

It was unknown if any action was taken with Durvalumab.

The patient died from the event diarrhea, nausea, on wednesday he got worse, patient did not get up and patient was no longer eating on 05-Jun-2025.

The patient died on 05-Jun-2025. It was not known whether an autopsy was performed. The cause of death was unknown.

The events were considered 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 and patient was no longer eating.

The company physician considered that there was a reasonable possibility of a causal relationship between Durvalumab and the following events: diarrhea, nausea, on wednesday he got worse, patient did not get up and patient was no longer eating.

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.