15. DAILY DOSE(S) #1) 1500 milligram, q4w #1) Intravenous use 16. ROUTE(S) OF ADMINISTRATION																					CIO	٥N	/IS	FΟ	RM
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FOLLOWUP:

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.