GILEAD	Post Market Query Template	GT-21043B (2.0)

Date: 13 June 2018

MCN: 2018-0341154

Dear Reporter,

To comply with our global regulatory reporting obligations and as part of our pharmacovigilance process, we are required to report adverse events that may be associated with our product. Patient confidentiality will be maintained in accordance with applicable laws/policies.*

We received the following report on **25-MAY-2018** for your patient who was treated with **Harvoni**.

Patient: **TD** DOB: **06-JUL-1961** Gender: **Male**

Adverse Event(s): **Death**

Please provide date of death
What was the cause of death?
Where there any other associated AEs?
Please confirm that year of drug start date is 2017 and not 2018.

Patient Information:

Initials: T.D ***Date of Birth:*** 06 July 1961 (DD/MMM/YYYY) ***Age Group:*** ☐ Child (<18 yrs.) ☐ Adult (≥ 18 yrs. < 65 yrs.) ☐ Elderly (≥ 65 yrs.)

Sex: ☒ Male ☐ Female

Race: ☒ Caucasian ☐ Hispanic ☐ Of African Descent ☐ Asian ☐ Other (specify) _____

Age at onset of event: 56 (yrs.) ***Height:*** _____ ☐ in ☐ cm ***Weight:*** _____ ☐ lb ☐ kg

	Adverse Event(s): Adverse Event Description (provide diagnosis, if known) **Append separate sheet, if necessary**	***Causality*** Was the event considered related to Gilead drug? (Yes/No)	***Resulted in*** (Check any that apply) [1](A) Hospitalization (B) Disability (C) Life-threatening (D) Congenital Anomaly [2](E) Death	***Outcome*** (A) Resolved (B) Not Resolved (C) Unknown (D) Fatal (died due to event)	***Event Start Date*** (DD/MMM/YYYY)	***Event Stop Date*** (DD/MMM/YYYY)
1.	Cancer in the lymph nodes	No	A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒	March, 2018	20 Apr 2018
2.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
3.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
4.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
5.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
6.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
7.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		
8.			A☐ B☐ C☐ D☐ E☐	A ☐ B ☐ C ☐ D ☐		

[1] **If Adverse event resulted in hospitalization, please provide dates:** _____ (DD/MMM/YYYY) **to** _____ (DD/MMM/YYYY)

[2]**For Fatal events please provide autopsy report and date of death:** _____ (DD/MMM/YYYY)

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Summary of Event(s) / Other Relevant Information:

Please provide a short summary of the event(s) and include any treatment given, **relevant medical history**, **risk factors**, and the results of any supportive laboratory data or other investigations (append results separately, if necessary). Patient underwent 24-week of HCV treatment. On May 22, 2018 physician addressed to the patient's family to conduct SVR and was informed that unfortunately, patient died on April 20, 2018 due to cancer in the lymph nodes.

If medical intervention was required to prevent the reported event becoming serious, please check here ☐ and briefly describe the clinical course.

Medication Details - including Gilead drug(s):

*List **all** medications (including non-prescription and herbal preparations) the patient was receiving at the time of the event(s). **Append separate sheet, if necessary.***

	Name	Dose	Route	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Indication	Lot/Batch No.	Suspect Drug* Yes/No
1.	Harvoni	400/90mg	PO	05 Dec, 2017	28 Feb 2018	Chronic HCV		
2.	Ribavirin	600mg	PO	05 Dec, 2017	28 Feb 2018	Chronic HCV		
3.								
4.								
5.								
6.								
7.								
8.								

Yes = Considered to be causally associated with the reported event(s) No = Considered to NOT be causally associated with the reported event(s)

Action taken with Gilead Drug(s):

Due to the event, was the dosage of the Gilead drug(s):

☐ Continued unchanged ☐ Discontinued ☐ Reduced (new dosage _____) ☐ Unknown

If the dose was reduced or drug discontinued, did the symptoms:

☐ Resolve ☐ Improve ☐ Remain the same

If the Gilead drug was restarted, did the event reappear? ☐ No ☐ Yes (please provide details)

If the requested information is not available, please provide a response to this query indicating that the requested information is not available.

Please respond via E-mail: Safety_FC@gilead.com or Fax: 1-650-522-5477

If you need to speak with someone, please call **650-522-5114** and leave a voice message **including the MCN number** noted on the form, the **Gilead product** involved, **your name**, and **your phone number**. Thank you for your assistance with this case.

Kind regards,
Jennifer Kelly