GILEAD

Drug Safety & Public Health

Date: 7 February 2017 **MCN:** 2017-0255564

Dear Giorgi Khatelishvili,

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 **27-JAN-2017** for your patient who was treated with **Harvoni**.

Patient: **GK** DOB: **05-AUG-1971** Age: **46** Gender: **Male**

Adverse Event(s): **Hyperbilirubinemia gastrointestinal bleeding [Gastrointestinal bleeding], Vein thrombosis, Hyperbilirubinemia gastrointestinal bleeding [Hyperbilirubinemia]**

Following review of the reported information, we would like to request additional information regarding the above mentioned events:

1. **Does patient have a history of esophageal varices, gastric or duodenal ulcers or gastrointestinal bleeding of any kind?**
2. **Is patient receiving aspirin, NSAIDs, anti-coagulation or anti-platelet therapy?**
3. **Please provide serum bilirubin levels at baseline and at time of occurrence of the fatal events**
4. **Does patient have a medical history of deep venous thrombosis or thromboembolic disease of any kind?**
5. **Please complete the following sections below:**

Patient Information:

Initials: GK ***Date of Birth:*** 05-08-71 (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: 46 **(yrs.)** ***Height:*** 176 ☐ **in** ☒ **cm** ***Weight:*** 86 ☐ **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. gastrointestinal bleeding	No	A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒	Unknown	17/01/17
2. Hyperbilirubinemia	No	A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒	Unknown	17/01/17
3. liver cirrhosis	No	A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒	Unknown	17/01/17
4. vein thrombosis	No	A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒	Unknown	17/01/17
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]**Hospitalization dates:** ____/____/_____ (DD MMM YYYY) **to** ____/____/_____ (DD MMM YYYY)

[2]**For Fatal events please provide autopsy report and date of death:** 17 (DD) / 01 (MMM) / 2017 (YYYY)

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).

Hyperbilirubinemia gastrointestinal bleeding, vein thrombosis the patient was relapsed and had history of liver cirrhosis before treatment initation
No Autopsy was performed

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. Sof/Led	400/90	PO	21-10-16	17-01-17	Chronic Hep C	WCZX	No
2.							
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,
Carmen Leung