GILEAD

Drug Safety & Public Health

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Date: 4 August 2016 **MCN:** 2016-0225727

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 **28-JUL-2016** for your patient who was treated with **LEDIPASVIR/SOFOSBUVIR**.

Patient: **MN** DOB: **11-MAR-1949** Age: **67** Gender: **Female**

Adverse Event(s): **Acute Liver Failure**

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

1. **Please complete the following sections below.**
2. **Please provide the patient's medical history, concomitant medications, test results and alternative causality, if any.**
3. **Please clarify if baseline liver disease (compensated vs. decompensated cirrhosis, Child-Pugh score), was this acute on chronic liver failure, any precipitating factors, any history of decompensation prior?**
4. **Please provide any relevant clinical course/diagnostic work up.**

Patient Information:

Initials: MN ***Date of Birth:*** 11 March 1949 (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: 67 ***(yrs.)*** ***Height:*** 167 ☐ **in** ☒ **cm** ***Weight:*** 65 ☐ **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. Death due to Acute Liver Failure	no	A☐ B☐ C☐ D☐ E☒	A ☐ B ☐ C ☐ D ☒		03-07-16
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]Hospitalization dates: ____/____/____ (DD MMM YYYY) **to** ____/____/____ (DD MMM YYYY)

[2]For Fatal events please provide autopsy report and date of death: 03 (DD) / 07 (MMM) / 2016 (YYYY)

*Please be aware that information provided to Gilead relating to you, may be used to comply with applicable laws and regulations. By providing us with information you are consenting to the control and processing of this personal or sensitive data by Gilead in accordance with applicable data protection laws and the Gilead privacy policy, available to you either on www.gilead.com/privacy or upon request.

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 dead due to acute liver failure 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	400mg/90mg	po	12-04-16	03-07-16	Chronic Hep C	WBGT	
2. Ribavirin	200mg	po	12-04-16	03-07-16	Chronic Hep C		
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,
Shirley Gardner

*Please be aware that information provided to Gilead relating to you, may be used to comply with applicable laws and regulations. By providing us with information you are consenting to the control and processing of this personal or sensitive data by Gilead in accordance with applicable data protection laws and the Gilead privacy policy, available to you either on www.gilead.com/privacy or upon request.