

**GILEAD****POST MARKETING ADVERSE EVENT REPORT
FORM (FOSTER CITY)****GF-21043B (2.0)**

Local ID:

Gilead MCN: 2015-0184943

Patient Information:

Initials: CT Date of Birth: 28- / 12 / 1955 Age Group: ☐ Child (< 18 yrs.) ☒ Caucasian
DD MMM YYYY ☒ Adult (≥ 18 yrs. < 65 yrs.) Race: ☐ Hispanic
☐ Elderly (≥ 65 yrs.) ☐ Of African Descent
Sex: ☒ Male ☐ Female ☐ Asian
☐ Other (specify) _____

Age at onset of event: 59 (yrs.) Height: 175 ☐ in ☒ cm Weight: 75 ☐ lb. ☒ kg

Adverse Event (s) or other Safety Information:

Adverse Event Description (provide diagnosis, if known)

Start Date
(DD/MON/YYYY)**Stop Date**
(DD/MON/YYYY)**Outcome**

(A) Resolved (D) Not resolved
(B) Resolved with sequelae (E) Died due to event
(C) Resolving (F) Unknown

1. Lung Cancer		2015/10/31	A ☐ B ☐ C ☐ D ☐ E ☒ F ☐
2.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
3.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
4.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
5.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐

Did the event(s) result in: ☒ Hospitalization ☐ Prolongation of hospitalization ☐ Significant disability
Was the event: ☐ Life threatening (immediate risk of death at time of event) ☐ Fatal (please provide autopsy report)
Date of death: ____/____/____

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, outcome, and the results of any supportive laboratory data or other investigations (append results separately, if necessary).

Patient started treatment 27-08-2015 and discontinued treatment after taking 1 pill of Sovaldi,
His death reason was not related to drug he had Lung cancer though there are no additional details
in regards of treatment of cancer he was smoker, though we dont have his
He had HCV3, his treatment regimen was 24 Weeks Sof+ Rib

If medical intervention was required to prevent the reported event becoming serious as defined above, please check here ☐ and provide reasons.

**GILEAD****POST MARKETING ADVERSE EVENT REPORT
FORM (FOSTER CITY)****GF-21043B (2.0)****SFMTD****Medication Details:**

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/MON/YYYY)	Stop Date (DD/MON/YYYY)	Indication	Lot/Batch No	Suspect ¹	Non- Suspect ²
1. Sovaldi	400mg		27-08-2015	31-10-2015		SFMTD		
2. Ribavirin	200mg		27-08-2015	31-10-2015				
3.								
4.								
5.								
6.								
7.								
8.								

¹Considered to be causally associated with the reported event(s)²Considered not to 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 (provide details): _____**Reporter Details:**

Name: _____

Address: _____

_____☐ Doctor☐ Nurse☐ Pharmacist☐ Consumer☒ Other, please specify: _____

Telephone: _____

Preferred method of contact:

☐ Mail☐ Fax☐ Email☐ Telephone

Fax: _____

Email: _____

☐ Other, please specify: _____

Signature: _____

Date: _____ (DD/MON/YYYY)

Gilead Representative Details (if applicable):

Name: _____

Responsible Region/Territory: _____

Email: _____

@gilead.com

Telephone: _____

Email or FAX Completed Form as soon possible to:

Or Report by:

Mail:

Gilead Sciences,
Drug Safety and Public Health
333 Lakeside Drive.,
Foster City, CA 94404 USAEmail: Safety_FC@gilead.com

Fax: +1-650-522-5477

Telephone: +1-800-445-3235 (USA)

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.