GILEAD

POST MARKETING ADVERSE EVENT REPORT FORM (FOSTER CITY)

GF-21043B (3.0)

Local ID: Gilead MCN: 2018-0331147

Patient Information:

Initials: M.A Date of Birth: 27 / 12 / 1969 (DD / MMM / YYYY)

Sex: ☒ Male ☐ Female

Age Group: ☐ Child (< 18 yrs.) ☒ Adult (≥ 18 yrs. < 65 yrs.) ☐ Elderly (≥ 65 yrs.)

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

Age at onset of event: 49 (yrs.) Height: 170 ☐ in ☒ cm Weight: 68 ☐ 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. Anemia	NO	A☐ B☐ C☐ D☐ E☐	A☐ B☐ C☐ D☐	1 Mar 2018	
2. Leucocytosis	NO	A☐ B☐ C☐ D☐ E☐	A☐ B☐ C☐ D☐	27 Mar 2018	
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 the 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)

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).

On 4th week of treatment, hemoglobin level was 11.0. On 12th week of treatment Hemoglobin level was 10.3. On March 27 patient had a temperature and by conduction of blood test Leycocytosis was revealed. Patient was directed to the Hematologist. After treatment with Harvoni patient was diagosed with Leukemia. Patient started chemotherapy.

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

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Medication Details:

2018-0331147

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 Drug* (Yes/No)
1. Harvoni	400/90mg	PO	4 JAN 2018	29 Mar 2018	Chronic HCV		
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 (provide details): _____

Reporter Details:

Name: _____

Address: _____

_____

_____

_____

Telephone: _____

Fax: _____

Email: _____

☐ Doctor ☐ Nurse ☐ Pharmacist ☐ Consumer

☐ Other, please specify: _____

Preferred method of contact:

☐ Mail ☐ Fax ☐ Email ☐ Telephone

☐ Other, please specify: _____

Signature: _____ _____ (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:

Email: Safety_FC@gilead.com

Fax: +1-650-522-5477

Or Report by:

Mail: Gilead Sciences,
Drug Safety and Public Health
333 Lakeside Drive.,
Foster City, CA 94404 USA

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.

HISTORY OF REVISIONS

Effective Date	Revision	Author	Description of Changes
Refer to EDMS	3.0	Grace Liu	Reformatted Adverse Events section: • Added reference to appending separate sheets. • Added column "Causality". • Added column "Resulted in". • Modified Outcome options. • Added "Hospitalisation dates" section.
25-Feb-2015	2.0	Li Hsu	Reverted title of form to "Post Marketing Adverse Event Report Form (Foster City)". Renamed from "Gender" to "Sex". Removed Special Situations section. Added medical intervention text to the Summary of Event(s) section. Added Gilead Representative Details section.
04-Sep-2013	01	Gary Saunders	Change title from "Post Marketing Adverse Event Report Form (Cambridge)". Addition of fields to collect SSR information and placeholder text for MCN number to be pre-populated from the safety database.
03-Aug-2011	00	Nicola Gilson	Converted from GF-21004F.05 to GF-21043A.00. Minor changes including addition of Race.