*Execution Copy*

**Memorandum of Understanding**

This Memorandum of Understanding (this "**MOU**") is effective as of April 21, 2015 (the "**Effective Date**") by and between Gilead Sciences Ireland UC ("**Gilead**") and the Ministry of Labour, Health and Social Affairs of the Republic of Georgia (the "**MOH**"). Gilead and MOH are each referred to individually herein as a "**Party**" and collectively as the "**Parties**."

1. Background. The Parties are collaborating with The Centers for Disease Control and Prevention of the United States ("**CDC**") to develop and implement a multi-year program aimed at eliminating Hepatitis C Infection ("**HCV**") in the Republic of Georgia, including anticipated treatment of up to 20,000 patients per year (the "**HCV Program**"). The Parties recognize that there is an urgent need to treat patients with HCV in the Republic of Georgia, and desire to commence treatment of up to 5,000 Qualified Patients (as defined below) under an initial program ("**Initial Program**") prior to finalizing the definitive agreement(s) for the broader HCV Program, all in accordance with the terms and conditions set forth below. The Parties acknowledge that MOH will carry out the Initial Program with the support of CDC pursuant to a separate Memorandum of Understanding between MOH and CDC.

2. Donation of Product. Gilead, directly or through a locally appointed agent in the Republic of Georgia, will supply to MOH, free of charge, bottles of Sovaldi (tablets of 400 mg of sofosbuvir) ("**Product**") in the quantities set forth in Section 8 below to treat up to 5,000 Qualified Patients (as defined below) in accordance with the terms of this MOU. Gilead's donation of Product hereunder is provided solely to advance the bona fide goals and objectives of the MOH, and is not intended to reward or influence, and is not contingent upon, the purchase, prescription, approval, recommendation, or other favorable treatment of Gilead's products by the MOH, CDC or any of their affiliated entities.

3. Qualified Patients. MOH agrees to distribute Product (a) only within the Republic of Georgia; (b) only to patients meeting mutually agreeable screening criteria focusing on those patients that are most in need (the "**Qualified Patients**") who will receive the Product at no cost (the "**Government Program**"); and (c) only for the treatment of HCV (whether mono-infected or co-infected, provided in each case that such treatment is consistent with the Product label and available data therefor). The Parties acknowledge and agree that MOH is committed to, and anticipates, treating Qualified Patients with the Product through the Government Program in a manner consistent with the Product label or treatment protocols that have been approved by the applicable regulatory authority in the Republic of Georgia, and in distributing the Product to Qualified Patients shall provide any additional documentation as may be required by such regulatory authority (e.g., local translations of Product documentation as provided by Gilead). MOH agrees to monitor each patient that initiates and/or completes treatment for HCV with Product supplied under this MOU to determine the outcomes of such treatment and provide Gilead with the reports specified in Section 4 below.

4. Reports; Meetings. MOH will provide Gilead with regular, and in any event at least monthly, reports on the progress of the Initial Program, including providing information on the number of patients initiating treatment, number of patients treated and cure rates, as well as such other information as Gilead may reasonably request. MOH shall obtain all information contained in the reports provided to Gilead in accordance with applicable laws, including applicable privacy laws. Gilead may use and disclose the reports provided by MOH (and the information contained therein) for any commercially reasonable purpose. In addition, the Parties will have meetings, which may include CDC, as reasonably necessary or

useful to coordinate on the activities under the Initial Program, including for purposes of developing and evaluating protocols for patient monitoring.

5. Program Integrity and Patient Compliance Plan. MOH shall implement a plan agreed to by Gilead, the primary purpose of which will be to minimize the possibility of diversion of Product outside of (a) the Government Program and/or (b) the Republic of Georgia (the "**Program Integrity and Patient Compliance Plan**"). The Parties acknowledge that they have agreed to a Program Integrity and Patient Compliance Plan as of the Effective Date, which such Program Integrity and Patient Compliance Plan will be reviewed by the Parties periodically, and updated as mutually agreed by the Parties to achieve the goals set forth in in this Section 5 above. During the term of this MOU, MOH will provide Gilead with a summary of any material outcomes associated with, or observed with respect to, the implementation of the Program Integrity and Patient Compliance_Plan, including whether MOH, to the best of its knowledge, has become aware of any diversion of Product outside of the Republic of Georgia or outside the scope of the Government Program.

6. Administration of Product. Unless the Program Integrity and Patient Compliance Plan specifies otherwise, Qualified Patients within the Government Program shall receive only one bottle (28 ct. tablets) of Product for each month of treatment.

7. Future Products. The Parties acknowledge that, as of the Effective Date, Gilead is in the process of submitting applications for marketing approval of Gilead's proprietary pharmaceutical product known as Harvoni (tablets of 400 mg sofosbuvir; 90 mg ledipasvir) for the treatment of HCV in the Republic of Georgia. Following receipt by Gilead of such marketing approval for Harvoni (and only following receipt of such marketing approval), Harvoni shall be deemed a Product under this MOU. MOH acknowledges and agrees that any Qualified Patient that has started a treatment regimen for HCV hereunder using Sovaldi will be required to finish his/her full course of treatment on Sovaldi pursuant to the label therefor.

8. Product Requests and Supply.

(a) Initial Product Request and Supply. MOH agrees to request from Gilead, and Gilead will supply, in accordance with Section 8(c) below, an initial quantity of up to 8,000 bottles of Product for delivery to the MOH within 30 days of the Effective Date.

(b) Additional Product Requests. MOH will place requests for additional Product with Gilead in minimum quantities of 1,000 bottles per request and will provide for a 180-day lead time. Without limiting the foregoing, Gilead will use its commercially reasonable efforts to supply Product hereunder as promptly as possible.

(c) General. MOH will submit a written request to Gilead on a mutually agreed upon form for any request of Product hereunder. All Product shipments will be delivered CIP (Incoterms 2010) to Tbilisi International Airport, Republic of Georgia (the "**Destination**"). Gilead will select the carrier, and bear the expenses for the delivery of Product to the Destination, including transportation and insurance costs. Title to and risk of loss for Products will transfer to MOH upon delivery at the Destination. MOH shall coordinate and otherwise be responsible for all other expenses and matters associated with the importation and distribution of Product within the Republic of Georgia, including all taxes, duties, customs, and clearances with respect to Product following delivery at the Destination. MOH is also responsible for observing the recommended storage and transportation conditions of the Product as per the instructions set out in the Product labeling.

9. Agreement(s) for HCV Program. The Parties acknowledge that this MOU is intended to cover the Initial Program only, and that any additional activities under the broader HCV Program will be subject to separate written agreement(s) between the Parties and CDC. During the term of this MOU, the Parties will use good faith, diligent efforts to enter into such agreement(s) for the HCV Program.

10. Term and Termination. The term of this MOU shall commence on the Effective Date and, unless terminated earlier in accordance with this Section 10, will expire upon (i) the first anniversary of the Effective Date, (ii) such time as 5,000 patients have been treated with Product hereunder, or (iii) the Parties enter into written agreement(s) for the HCV Program, whichever occurs first. Either Party may terminate this MOU upon written notice to the other Party in the event that such other Party shall have materially breached this MOU, and such breach is not cured within 30 days after receiving written notice specifying such breach. If MOH is the breaching Party, then Gilead will not be obligated to continue to supply Product following termination of the MOU, except to the extent necessary for Qualified Patients who are receiving therapy at the time of the termination to complete their prescribed course of therapy in accordance with the Product's approved label or treatment protocols. Sections 3 and 10 – 16 will survive any termination or expiration of this MOU.

11. Drug Safety Reporting.

(a) MOH will report all safety information in English to Gilead, on the reporting form provided by Gilead from time to time, which includes, but is not limited to, all adverse events ("**AE**"), serious adverse events ("**SAE**"), or Special Situation Reports (reference Exhibit A for definitions) of which MOH becomes aware during the term of this MOU within one (1) business day of becoming aware of such report. Any reports addressed to Gilead should be sent to the attention of:

Gilead Sciences, Inc.
Drug Safety & Public Health
333 Lakeside Dr.
Foster City, CA 94404
Fax: 650.522.5477
Tel: 650.522.5114
E-mail: Safety_FC@gilead.com

(b) With all reports, where the contact is not a healthcare provider, MOH will provide Gilead with the contact details of the relevant healthcare professional wherever possible, in order that medical confirmation and causality can be determined.

(c) Upon Gilead's request MOH will provide Gilead with all reasonable assistance in obtaining any further information required by Gilead to perform medical assessments of any safety information. Gilead will send any such request for additional information to MOH's appointed representative, to be identified promptly following the Effective Date (and in any event prior to the first shipment of Product hereunder).

(d) The Parties agree that MOH will be responsible for any regulatory reporting obligations that arise from the receipt and processing of the individual case reports received in Georgia and Gilead or its third party designee will manage reporting obligations to meet worldwide regulatory reporting requirements.

(e) Each calendar quarter and upon expiry or termination of this MOU MOH will provide a summary of all safety information that MOH has sent to Gilead, for reconciliation purposes, on the form provided to: standards.&collaborationsDSPH@gilead.com.

(f) Gilead will provide, at mutually agreeable times, training materials for MOH on the safety reporting requirements. All employees involved in the program must complete the training and the certification at least annually. Training certificates should be forwarded by e-mail to Gilead Standards and Collaborations: standards.&collaborationsDSPH@gilead.com.

12. Indemnification. Each Party hereby agrees to indemnify, defend and hold the other Party harmless from and against any and all losses, liabilities, costs and expenses arising from third party claims as a result of such Party's material breach of this MOU, except to the extent such losses result from the negligence or willful misconduct of the other Party.

13. Limitation of Liability. GILEAD SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, PUNITIVE OR INDIRECT DAMAGES IN CONNECTION WITH THIS MOU WHETHER FORESEEABLE OR NOT, AND WHETHER ARISING IN CONTRACT, TORT, OR NEGLIGENCE. For clarity, nothing in this Section 13 shall be construed to limit Gilead's obligation to continue to supply Product following termination of this MOU for MOH's breach to the extent necessary for Qualified Patients who are receiving therapy at the time of the termination to complete their prescribed course of therapy in accordance with the Product's approved label or treatment protocols as set forth in Section 10 above.

14. Confidentiality. This MOU and all information disclosed by one Party to the other in relation to this MOU shall be treated by the Parties as confidential. Unless expressly authorized in this MOU or by the disclosing Party to do so, the receiving Party shall not disclose to third parties any information disclosed by the other Party under this MOU. The obligations under this Section 14 shall not apply to the extent that any such information becomes part of the public domain without breach of this Section 14 by the receiving Party.

15. Governing Law; Arbitration. This MOU will be governed by and construed in accordance with the laws of England and Wales, without regard to any conflict of laws provisions. The Parties agree that any dispute or controversy arising out of, in relation to, or in connection with this MOU, shall be finally settled by binding arbitration in London, England under the then current rules of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with such rules. The decision of the arbitrator shall be final, conclusive and binding on the Parties. Judgment may be entered on the arbitrator's decision in any court of competent jurisdiction. The written decision of the panel of arbitrators shall be final, conclusive, and binding on the parties and may be enforced in any court of competent jurisdiction. Each Party shall bear its own costs in respect of the arbitration, including administrative and arbitrator's fees.

16. Miscellaneous. This MOU constitutes the entire and only agreement between the Parties relating to the subject matter hereof, and supersedes all prior negotiations, representations, agreements and understandings with respect to such subject matter. No agreements altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of each Party. Nothing in this MOU shall be construed to grant to MOH any license to use Gilead's name trademarks, or logo, in any format. All obligations of the Parties with respect to the subject matter set forth herein are set forth in this MOU. Each Party agrees to perform its obligations under this MOU in

accordance with all applicable laws, rules and regulations. No Party may transfer or assign this MOU to a third party without the prior written consent of the other Parties, except that Gilead may transfer or assign this MOU to an affiliate of Gilead without prior written consent from the other Parties.

IN WITNESS WHEREOF, authorized representatives of the Parties have executed this Memorandum of Understanding as of the Effective Date.

**ON BEHALF OF**
**GILEAD SCIENCES IRELAND UC**

By:_____

Name: John C. Martin, Ph.D.

Title: Chairman and Chief Executive Officer, Gilead Sciences, Inc.

By:_____

Name: Gregg H. Alton

Title: Executive Vice President, Corporate and Medical Affairs, Gilead Sciences, Inc.

**ON BEHALF OF THE MINISTRY OF LABOUR, HEALTH AND SOCIAL AFFAIRS OF GEORGIA**

By:_____

Name: Irakli Garibashvili

Title: Prime Minister of Georgia

By:_____

Name: Davit Sergeenko

Title: Minister of Labour, Health and Social Affairs

## Exhibit A

## Drug Safety Definitions

**Abuse:** Persistent or sporadic intentional excessive use of a Medicinal Product by a patient or Clinical Trial subject.

**Adverse Event ("AE"):** Any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event (AE) can therefore be any unfavourable and/or unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs may also include pre- or post-treatment complications that occur as a result of protocol mandated procedures, lack of efficacy, Overdose or drug Abuse/Misuse reports. Pre-existing events that increase in severity or change in nature during or as a consequence of participation in the clinical study shall also be considered AEs.

**Adverse Reaction ("AR"):** An untoward medical occurrence (unintended or noxious responses) considered causally related to an investigational or authorized medicinal product at any dose administered. Adverse Reactions may arise from Medication Errors, uses outside what is foreseen in the protocol or prescribing information (off-label use), Misuse and Abuse of the product, Overdose or Occupational Exposure where applicable.

**Lack of Effect Report:** A report of a situation where there is apparent failure of the medicinal product or medical technology to bring about the intended beneficial effect on individuals in a defined population with a given medical problem, under ideal conditions of use. NOTE: Lack of Effect reports from Clinical Studies refer to situations where the product is administered within the authorized indication and use.

**Medication Error**: Any unintentional error in the prescribing, dispensing or administration of a medicinal product while the medication is in the control of a healthcare professional, patient or consumer.

**Misuse:** Use of a medicinal product that is intentional and inappropriate and not in accordance with its authorized product information.

**Occupational Exposure:** Exposure to a medicinal product as a result of one's professional or non-professional occupation.

**Off-label Use:** Where a medicinal product is intentionally prescribed by a Health Care Professional for a medical purpose not in accordance with the authorized product information with respect to indication, dose or patient population (e.g. the elderly). NOTE: Off- Label Use will not apply in Clinical Studies.

**Overdose:** Administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose as per the protocol or in the product labelling. The Parties agree that in the course of conducting a clinical study, the terms of the clinical study protocol (as fully approved by all applicable bodies) overrides the local product labelling.

**Pregnancy Reports:** Reports of pregnancy following maternal or paternal exposure to the product.

**Product Complaints:** Complaints arising from potential deviations in the manufacture, packaging or

distribution of the medicinal product.

**Serious Adverse Event ("SAE") / Serious Adverse Reaction ("SAR"):** An event or any untoward medical occurrence that at any dose either:

a) Results in death; or
b) Is life-threatening

*NOTE:* The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe; or

c) Requires in-patient hospitalisation or prolongation of existing hospitalisation; or
d) Results in persistent or significant disability/incapacity; or
e) Results in a congenital anomaly/birth defect; or
f) Results in a medically important event or reaction.

*NOTE:* medically important event**:** AEs requiring medical and scientific judgment to determine if expedited reporting is appropriate. Such events may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes constituting SAEs. Medical and scientific judgement should be exercised in deciding whether an event is a medically important event. Examples of medically important events include intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug Abuse. For the avoidance of doubt, infections resulting from contaminated medicinal product shall be considered a medically important event and subject to expedited reporting requirements.

**Special Situation Reports ("SSR"):** One of a) Pregnancy, b) Abuse, c) Medication Error, d) Misuse, e) Off-Label Use, f) Overdose, g) Lack of Effect, h) AEs in infants following exposure from breastfeeding, i) AEs associated with Product Complaints or arising from Occupational Exposure. For the avoidance of doubt this applies to all reports including reports in a pediatric or elderly population.

***NOTE:*** This is not an exhaustive list and any safety information should be reported to Gilead's Drug Safety Public Health (DSPH).