

Witness Name: Phillip Wellman

Statement No: WITN1997001 Exhibits:

WITN1997002 – WITN1997010

Dated: 27.08.2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN1997009

PLEASE SEND THIS FORM COMPLETED & SIGNED TO IDIS

For country specific Idis contact details please visit the below website or refer to the contact list provided at end of this form.
<http://www.idispharma.com/pharmacist-contact-us.php>

TELAPREVIR NAMED PATIENT PROGRAM
Physician Declaration Form

Please read the physician information pack provided and the following Eligibility and Non-Eligibility criteria for the supply of TELAPREVIR. Complete and sign the following declaration and return the form to Idis on the contacts details above.

PATIENT TREATMENT CRITERIA

Patient Initials: FW (first letter first name, first letter family name) OR unique number

Date of Birth: GRO-C 46 (DD-MMM-YY)

Eligibility criteria	Yes	No
Be a man or woman, between 18 and 70 years of age, inclusive	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Have evidence of HCV infection genotype 1 (molecular assay)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Have a quantifiable plasma HCV RNA	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Have documentation of liver fibrosis assessed by liver biopsy or non-invasive test (eg, fibrotest, fibroscan) showing severe fibrosis (Metavir F3 or Ishak 3-4) or cirrhosis (Metavir F4 or Ishak 5-6). For subjects with Metavir F3 or Ishak 3-4, the liver biopsy or non-invasive test should have been performed within the past 18 months.	<input type="checkbox"/>	<input checked="" type="checkbox"/> *
Have compensated liver disease (Child-Pugh Grade A clinical classification)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Have access to the Hepatitis C standard of care (Peg-IFN-alfa/RBV)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If a women of childbearing potential, must have a negative serum β -human chorionic gonadotropin (β -hCG) pregnancy test documented at the screening visit and a negative serum or urine pregnancy test before the first dose of study drug to ensure that they are not pregnant at the time of starting treatment.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If heterosexually active, a female subject of childbearing potential and a nonvasectomized male subject who has a female partner of childbearing potential must agree to use 2 effective contraceptives from screening onwards until 4 months (female subject) or 7 months (male subject) after all therapy has ended. Note: Hormonal contraceptives may not be reliable during TELAPREVIR dosing. Therefore, to be eligible for this early access program, subjects should use 2 other effective birth control methods during TELAPREVIR combination therapy and for 2 months after the last intake of TELAPREVIR.	<input type="checkbox"/>	<input type="checkbox"/>

Non eligibility criteria	Yes	No
Is eligible for enrollment into an ongoing clinical study of TELAPREVIR	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is infected or co-infected with HCV of another genotype than genotype 1	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a contraindication to the administration of Peg-IFN-alfa or RBV, or medical history or laboratory values that preclude treatment with Peg-IFN-alfa or RBV according to the respective local prescribing information	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a history of having received investigational HCV protease or polymerase inhibitors at any previous time	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has signs or symptoms of hepatocellular carcinoma. Serum alpha-fetoprotein (AFP) level and ultrasonography should be available at screening for all subjects to screen for hepatocellular carcinoma (both tests should have been done a maximum of 4 months before the screening visit).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a history of decompensated liver disease: history of ascites, hepatic encephalopathy, or bleeding esophageal varices, and/or any of the following screening laboratory results: <ul style="list-style-type: none"> • International Normalized Ratio (INR) of ≥ 1.5 • Serum albumin < 3.3 g/dL • Serum total bilirubin > 1.8 times the upper limit of the laboratory normal range, unless isolated or in subjects with Gilbert's Syndrome. 	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a co-infection with active hepatitis B or HIV	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has any of the following laboratory abnormalities (assessed at local laboratory) as defined by the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS): <ul style="list-style-type: none"> • Absolute neutrophil count (ANC) $< 1,500$ cells/mm³ • Platelet count $< 90,000$ cells/mm³ • Hemoglobin concentration < 12 g/dL in females or < 13 g/dL in males • Calculated creatinine clearance < 50 mL/min • potassium < 3.5 mmol/L 	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has inadequately controlled thyroid function (TSH)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has baseline increased risk for anemia (eg, thalassemia, sickle cell anemia, spherocytosis, history of gastrointestinal bleeding) or for whom anemia would be medically problematic	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has congenital QT prolongation or family history of congenital QT prolongation or sudden death	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a history of severe psychiatric disease, including psychosis and/or depression, characterized by a suicide attempt, hospitalization for psychiatric disease, or a period of disability as a result of psychiatric disease	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a history of immunologically mediated disease (eg, inflammatory bowel disease, idiopathic thrombocytopenic purpura, lupus erythematosus, autoimmune hemolytic anemia, scleroderma, severe psoriasis [defined as affecting $> 10\%$ of the body, where the palm of one hand equals 1%, or if the hands and feet are affected], rheumatoid arthritis requiring more than intermittent nonsteroidal anti inflammatory medications for management)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has clinical evidence of chronic pulmonary disease associated with functional impairment	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a history of uncontrolled severe seizure disorders	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Non eligibility criteria	Yes	No
Has a history or other evidence of a clinically relevant ophthalmologic disorder due to diabetes mellitus or hypertension or history or other evidence of severe retinopathy (eg, cytomegalovirus, macular degeneration)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has a history of major organ transplantation with an existing functional graft with the exception of corneal transplants and skin grafts	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is currently enrolled in an investigational drug study or has participated in such a study within 30 days before Day 1	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is a woman who is pregnant or breast-feeding	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has any condition that, in the opinion of the investigator, would compromise the well being of the subject.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Administration requirements and safety recommendations

- TELAPREVIR must not be administered as monotherapy and must only be prescribed in combination with both Peg-IFN-alfa and RBV.
- TELAPREVIR must not be restarted if discontinued.
- Telaprevir dose must not be reduced.
- The duration of therapy with standard of care (Peg-IFN-alfa/RBV) will vary by early virologic response and/or by type of subject (treatment naïve or prior treatment relapsers, or previously treated with prior partial or prior null response, or who had viral breakthrough; and Metavir/ishak score).
- HCV RNA levels should be monitored at weeks 4 and 12 and as clinically indicated.
- The following laboratory evaluations (complete blood count with white blood cell differential counts, electrolytes, serum creatinine, liver function tests, TSH, uric acid) must be conducted in all patients prior to initiating TELAPREVIR combination treatment. These are recommended baseline values for initiation of TELAPREVIR combination treatment: Hemoglobin: ≥ 12 g/dL (females); ≥ 13 g/dL (males); Platelet count $\geq 90,000/\text{mm}^3$; Absolute neutrophil counts $\geq 1,500/\text{mm}^3$; Adequately controlled thyroid function (TSH); Calculated creatinine clearance ≥ 50 mL/min; Potassium ≥ 3.5 mmol/L.
- Hematology evaluations (including white cell differential count) are recommended at weeks 2, 4, 8, and 12 and as clinically appropriate thereafter.
- Chemistry evaluations (electrolytes, serum creatinine, uric acid, hepatic enzymes, bilirubin, and TSH) are recommended as frequently as the hematology evaluations or as clinically indicated.
- Electrolyte disturbances (e.g., hypokalemia, hypomagnesemia and hypocalcemia) should be monitored and corrected, if necessary, prior to initiation and during TELAPREVIR therapy.

Administration requirements and safety recommendations

- Discontinuation of TELAPREVIR combination treatment is not required for mild and moderate rash. Patients experiencing mild to moderate rash should be monitored for signs of progression.
- If a severe rash (defined as involving more than 50% of body surface area) occurs, TELAPREVIR must be discontinued immediately; Peg-IFN-alfa and RBV may be continued. If improvement is not observed within 7 days of TELAPREVIR discontinuation, sequential or simultaneous interruption or discontinuation of RBV and/or Peg-IFN-alfa should be considered; if medically indicated, earlier interruption or discontinuation of Peg-IFN-alfa and RBV may be needed.
- Any rash that is associated with significant systemic symptoms, mucous membrane ulceration, target lesions, epidermal detachment, vesicles, or bullae constitutes a severe skin reaction and requires immediate and permanent discontinuation of TELAPREVIR, Peg-IFN-alfa, and RBV.
- Hemoglobin should be monitored at regular intervals prior to and during TELAPREVIR combination treatment.
 - For the management of anemia, refer to the prescribing information for RBV for its dose reduction guidelines.
 - If RBV is permanently discontinued for the management of anemia, TELAPREVIR must also be permanently discontinued. If TELAPREVIR is discontinued for anemia, patients may continue treatment with Peg-IFN-alfa and RBV.
 - Ribavirin may be restarted per the dosing modification guidelines for RBV. The dose of TELAPREVIR must not be reduced and TELAPREVIR must not be restarted if discontinued.

Order Information

☒ ORDER (tick box): Please supply 12 bottles, each containing 42 tablets of 375 mg tablets TELAPREVIR. This provides medication for 1 patient for 12 weeks (minimum order quantity = 12 bottles).

Delivery Details

Pharmacist Helen Cooper (full name/title)

Contact Telephone Number GRO-C ☒ GRO-C GRO-C

Delivery Address:

Name hospital/pharmacy Royal Free NHS Trust

Street/number Rowland Street

Post code NW3 2PQ

City London

Country England United Kingdom

Physician Declaration

1. I confirm that I accept full legal liability and responsibility for the use of TELAPREVIR for this patient under my care and that I have appropriate qualification and expertise for administering TELAPREVIR.
2. All information disclosed within the context of the TELAPREVIR Early Access Program shall be treated as confidential by me and shall only be used for the purpose of the TELAPREVIR Early Access Program supply.
3. I have requested supply of TELAPREVIR for this patient on a named patient basis for the treatment of genotype 1 chronic Hepatitis C with severe fibrosis or compensated cirrhosis. I have informed the patient that TELAPREVIR is provided on a named patient basis and is not currently approved in my country according to local laws.
4. I confirm to have checked laboratory tests (complete blood count with white blood cell differential counts, electrolytes, serum creatinine, liver function tests, TSH, uric acid) before starting TELAPREVIR. And these tests will be monitored on a regular basis according to safety warnings.
5. I confirm that unused or expired tablets of TELAPREVIR will be destroyed according local procedures.
6. I have informed the patient that the information provided in this Physician Declaration Form may be provided to Janssen and its affiliates for operational purposes only.
7. I have read and understood the documents provided in the TELAPREVIR Physician Access Package, including prescribing and patient monitoring requirements, and specific storage and administration requirements for TELAPREVIR.
8. I understand that I will be contacted by a qualified local Janssen representative before administering the first dose of TELAPREVIR to a patient.
9. I understand that all Serious Adverse Events (SAE) and non-serious Adverse Drug Reactions (ADR) that occur while the patient is being treated with the Named Patient supply of medication must be sent to the Janssen Local Safety Officer as instructed on the top of the SAE/ADR form.

Treating Physician's Name Gert Janssen (full name/title)

Contact Telephone Number GRO-C

Treating Physician's Registration/License Number 887 4263

Name hospital/pharmacy ROYAL Free

Street/number NW8 2AQ

Post code London

City UK

Country GRO-C

Treating Physician's Signature GRO-C

Date (DD/MM/YY) 1/6/11

Idis Country Contact List

If your country or language is not listed below please use the following contact:

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