

Witness Name: Ingrid Western

Statement No.: WITN2062001

Exhibits: WITN2062002-

WITN2062024

Dated: 14 August 2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN2062017

CLINICAL TRIALS SERVICE - DR KOSH AGARWAL

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
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Clinical Trial Clinic (Viral Hepatitis) - Dr. K. Agarwal BMed Sci(Hons) MD
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Clinic Date: 13/03/2014

PRIVATE AND CONFIDENTIAL

Dr Ansell
Chomley Gardens Surgery
1 Chomley Gardens
Mill Lane, London
NW6 1AE

Dear Dr Ansell

Ingrid WESTERN, DOB  1960, Hospital No: P564546, NHS No:





Re: GS-US-337-0124 - A Phase 2, Multicenter, Open-Label Study to Investigate the Safety and Efficacy of Sofosbuvir/Ledipasvir Fixed-Dose Combination + Ribavirin Administered in Subjects Infected with Chronic HCV who have Advanced Liver Disease or are Post-Liver Transplant

I am writing to inform you that your patient Ms Western was enrolled in a clinical study which I am currently running in my clinic. The study is a Phase 2, open-label study which will investigate the safety and efficacy of Sofosbuvir/Ledipasvir Fixed-Dose Combination (SOF/LDV FDC) (experimental drug) with Ribavirin (RBV) as a possible treatment for patients with chronic genotype 1 or 4 HCV infection who have Advanced Liver Disease or are Post-Liver Transplant.

Gilead Sciences Inc. is funding the study, and this study is being conducted in Australia, Canada, New Zealand, and various European countries.

GS-US-337-0124 Gilead Sciences Inc.
GP Letter Version 2.0_16th January 2014

This is a Phase 2 study designed to explore the efficacy and safety of the SOF/LDV FDC tablet with RBV in a population of subjects who have advanced hepatic disease. Subjects with advanced disease are often excluded from clinical trials. However, it is also recognised that when new therapies become available, the therapies are going to be used quickly in these difficult-to-treat subjects. Therefore, it is appropriate to explore the efficacy and safety of this new regimen in a formal clinical study, so that the data can provide guidance to physicians.

Subjects are randomised in a 1:1 ratio to receive either 12 or 24 weeks of dosing with SOF/LDV FDC (given once daily) + RBV (given as a divided dose twice daily).


The following medications are prohibited during the screening period and for a minimum of 28 days prior to the Day 1 visit through the end of treatment:

- Chronic use of systemic immunosuppressants including, but not limited to, corticosteroids (prednisone equivalent of > 10 mg/day for > 2 weeks), azathioprine, or monoclonal antibodies (eg, infliximab). In Cohort B, corticosteroids at higher doses may be used for short periods as clinically necessary to treat episodes of acute rejection.
- Investigational agents or devices for any indication
- Drugs disallowed per prescribing information of RBV
- Concomitant use of certain medications or herbal/natural supplements (inhibitors or inducers of drug transporters ie, P-gp) with study drug(s) may result in PK interactions resulting in increases or decreases in exposure of study drug(s). Examples of representative medications which are prohibited from 28 days prior to Day 1 through the end of treatment are listed below:

Drug Class	Agents Disallowed	Use with Caution (prescribe only when medically relevant)
Acid Reducing Agents	Proton- Pump Inhibitors	H2-Receptor Antagonists Antacids
Antiarrhythmics		Quinidine
Anticonvulsants	Phenobarbital, Phenytoin, Carbamazepine, Oxcarbazepine	
Antimycobacterials	Rifabutin, Rifapentine, Rifampin	
Cardiac Medications		Valsartan, Olmesartan, Telmisartan, Ranolazine, Bosentan, Digoxin
Herbal/Natural Supplements	St. John's Wort, Echinacea, Milk thistle (i.e., silymarin), Chinese herb sho-saiko-to (or Xiao-Shai-Hu-Tang)	
HMG-CoA Reductase Inhibitors	Rosuvastatin	Atorvastatin (< 10 mg per day), Simvastatin, Pravastatin, Pitavastatin, Fluvastatin, Lovastatin
Other	Modafinil	

NHS Confidential: Personal data about a patient

King's College Hospital 
NHS Foundation Trust

If you know of any reasons why this patient should not participate in this trial or have information that you think may be relevant to the patient's participation in the trial, please contact Gln Lee on  **GRO-C**

During the trial any adverse reactions will need to be recorded so please let us know if the patient experiences any of these during the study.

This trial has been approved by an Ethics Committee and the Regulatory Authority (MHRA). It is conducted in compliance with Good Clinical Practice, the Declaration of Helsinki and UK Legislation.

I enclose a copy of the patient information sheet for your information.

Yours sincerely

Electronically checked to avoid delay

 **GRO-C**

Dr Kosh Agarwal BMed.Sci (Hons) MD FRCP (Ed)
Consultant Hepatologist

Cc: