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Informed Consent Form for participants in the REDEMPTION-2 eTrial

Investigators: Dr James Freeman, MB, BS, B.Med Sci;
Mr Greg Jefferys, MA, PhDc.
Organisation: FixHepC Buyers Club Pty Ltd
eTrial Name: REDEMPTION-2
Medication: Sofosbuvir 400 mg / Daclatasvir 60 mg
Placebo: None
eTrial Type: Open Label
Suppliers: Incepta, Beacon, Julphar, Cipla, Hetero, and Natco – subject to availability
Eligibility: Genotype 1 2 3 4 5 6 patients
Cost: \$1500 USD per 12 week eTrial Subscription
Primary Outcomes: On treatment RVR, EOT, SVR12
Secondary Outcome: Real time side effect monitoring
Tertiary Outcome: Comparative performance of different generics.

Information Brief

Background

Hepatitis C is a blood-borne virus that causes inflammation of the liver. The virus is present in the blood of an infected person and can be spread through blood-to-blood contact. Around the world 185 million people have it making it a global health crisis on par with HIV, HBV, TB and Malaria.

Prior to 1988 Hepatitis C was known as non-A, non-B hepatitis. We did not have a test for it until 1991 meaning that in the 1970s and 1980s many people unwittingly contracted it, not from IV drug use but from blood transfusions and tattoos. Some patients contracted it at birth, and others from occupational exposure to blood.

Long term about 10% of people with Hepatitis C will die of complications including cirrhosis of the liver and liver cancer. Most people with the disease suffer a long-term chronic fatigue and carry with them an ever-present fear of infecting close contacts.

Up until recently treatments for Hepatitis C were problematic and sufferer from 5 main issues:

- Poor cure rates of < 50%
- Prolonged treatment times of 26-52 weeks
- Limited access due to the need for regular injections
- Limited access due to the high cost and resource limitations (waiting lists)
- Extremely unpleasant side effect leading many who have been treated to rate the treatment as being worse than the disease

Recently 12 week combination oral treatments have become available. These treatments have the advantages of:

- Once daily oral tablet delivery suitable for outpatient treatment
- High cure rates > 90% for most patients
- Minimal side effects
- 12 week (84 day) treatment duration for most patients

Unfortunately the current price tag is about \$84,000 USD per patient.

Fortunately several countries including the manufacturing powerhouses India, China and Bangladesh do not recognize the patent and produce these medications at 1/50th of the price meaning it's possible to get treated for less than \$2000 USD, rather than \$84,000 USD.

Purpose

OEM Sofosbuvir/Daclatasvir has been proven to cure 90-95% of Hep C sufferers, however few trials have been properly conducted using generic equivalents.

The purpose of this research is twofold:

- 1) To demonstrate the efficacy of generic Sofosbuvir/Daclatasvir in treating Hep C; and
- 2) To immediately treat and cure thousands of Hep C sufferers who are unable to purchase the patented version of this medication at \$84,000.

We will be recruiting 3,000 participants, making this eTrial the largest of its kind, and indeed the largest ever single trial of this medication. Most significantly however, the transparency and efficiency inherent to how this eTrial is being delivered will ultimately achieve FixHepC's primary mission - to assist millions of Hepatitis C sufferers obtain an effective, low-cost cure.

Process

This trial is essentially a documented treatment program for Hepatitis C sufferers using generic medication – no placebos will be used.

We will assist you with your purchase and personal importation of a 12 or 24-week treatment program using generic Sofosbuvir/Daclatasvir produced by a proven and reputable manufacturer, for example Incepta, Beacon and Julphar in Bangladesh and Cipla, Hetero and Natco in India if Daclatasvir becomes available there..

To subscribe as a participant you will need to:

- 1) Discuss the trial with your doctor - the risks, benefits and costs. If you require a GP for this purpose, you may use an online doctor service like GP2U Telehealth <https://gp2u.com.au/>, or MonkMed <http://www.monkmed.com/>, both of whom are supporting the trial.
- 2) Have your doctor provide the required prescription and arrange baseline blood tests;
- 3) Complete the Informed Consent Form (this form);
- 4) Pay the \$1500 USD eTrial subscription (\$3000 USD for 24 weeks treatment);
- 5) Submit your details online via the <http://www.monkmed.com/redemption2> website;
- 6) Submit this form, photo ID and your prescription to club@fixhepc.com
- 7) You will then receive a tracking number by email to follow the progress of your medication.

During the treatment period, you agree to use a self service online portal to lodge your results for on treatment Rapid Viral Response (RVR), End Of Treatment (EOT) and SVR12 to enable analysis of results.

Other Matters

Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not and you are free to withdraw at any time.

Personal Importation

Medication supply will be contingent on your country allowing your personal importation of medication. If your country prohibits this, but allows hand carriage of medication back into your country of origin participation will still be possible, but medication pickup will be in either India or Australia.

Side Effects

These medications can have unwanted effects, such as headaches, insomnia, fatigue, rash and gastrointestinal disturbances. In rare cases they cause more significant adverse effects up to and including death. You should consult with your doctor about your suitability to participate, or in the event of any adverse reactions to treatment.

Risks

Deaths have been reported in many of the trials of the new Hepatitis C medications, as have heart attacks, renal failure and other significant life threatening events.

Despite hundreds of successful treatments over the past 9 months using generic medication, the risk of not being cured is real. There is absolutely no guarantee that treatment will be successful in every case. There are no reimbursements if your treatment is not successful, however we will assist you sourcing more medications for re-treatment.

Benefits

The benefits to participating in this trial are clear – there is a very strong possibility that your Hepatitis C will be cured and the quality of your life will improve substantially.

Further, by proving the efficacy of low cost generic Hepatitis C medication this eTrial will help accelerate the treatment of the estimated 185 million Hepatitis C sufferers globally.

Confidentiality

The personal information that we collect from participants' registration is to assist with managing large volumes of participants in an efficient and cost-effective manner. This information will be stored securely and remain confidential. Only the necessary trial researchers and managers will have access to this information and any publicly available data will maintain your anonymity.

The information that you are required to post during the treatment program will not be aggregated with other participant's posts in order to synthesize meaningful outcome results.

Acceptance into this eTrial is not Guaranteed

We will not be cherry picking participants to bias the results, however we do expect this trial to be over-subscribed so cannot guarantee accepting your subscription. Subscriptions will be processed in order of arrival of payment. If you cannot be accepted your money will be refunded in full.

Contact

All questions before, during and after the trial should be directed to FixHepC Buyer’s Club at +61 (0) 3 8672 7825 or help@fixhepc.com.

Certificate of Consent

I, (name)

of (address)

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have read the foregoing information and the FixHepC website, and discussed this treatment option with my doctor. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this trial.

I give authorisation for FixHepC Buyers Club Pty Ltd to undertake the following on my behalf in regard to my treatment:

- 1. Order from a reputable supplier Sofosbuvir 400 mg / Daclatasvir 60 mg tablets
- 2. Assist in having this medication delivered to my nominated address

I understand the amount paid to FixHepC Buyers Club by me, will be used to cover the costs of the medication, packaging, shipping and handling, and eTrial administration and will be fully refunded in the event my subscription can, for any reason, not be processed.

I understand that in the event my medication is seized by customs I will be able to pick up replacement medication free of charge in India, and possibly other countries.

I am over 18 and my birthdate is

Signed

Date

Email

Phone

Payments can be made via wire transfer of \$1500 USD (12 weeks) or \$3000 USD (24 weeks) to:

Bank: Westpac Bank

Account Name: FixHepC Buyers Club Pty Ltd ABN 36 608 192 936

Address: Wellington Centre

15/60 Liverpool Street

Hobart TAS 7000, Australia

Account Designator: Trust Account

Home Branch Name: Hobart Office

BSB: 037001

Account No: 689777

SWIFT: WPACAU2S

IMPORTANT - PLEASE IDENTIFY YOUR PAYMENT WITH YOUR NAME and DATE OF BIRTH

Please return the completed form via email to club@fixhepc.com.

Please remember to include photo ID when you submit the form.

Checklist

- Completed consent form, photo ID and your prescription sent to club@fixhepc.com
- Registered on the <http://www.monkmed.com/redemption2> website
- Wire transfer \$1500 USD (12 weeks) or \$3000 USD (24 weeks) to FixHepC Buyers Club