Hemophilia Patients Urge NIH & IRB To Stop Ineffective Hepatitis C Trial

An open letter from People with Bleeding Disorders and HCV urging the U.S. government to stop clinical trials on a potentially damaging hepatitis C treatment.

April 23, 2014 By John Reed , Paul Brayshaw and Mark Antell

Below is a letter from People with Bleeding Disorders and HCV, to the Institutional Review Board (IRB) and National Heart, Lung, and Blood Institute (NIH) office recommending to end recruitment of a clinical study (pINF+RIBA+Telaprevir). People with Bleeding Disorders feel that this study is out-dated and mediocre therapy for Hepatitis C (HCV).

TO: Institutional Review Board, University of Cincinnati

C/O Jo Ann Behrle, joann.behrle@uc.edu UC-IRB contact for Emergency Medicine, Infectious Diseases, Neurology and Psychiatry

TO: NHLBI Sponsor, W. Keith Hoots MD, Director, Division of Blood Diseases and Resources at the National Heart, Lung, and Blood Institute

RE: Clinical study entitled "Viral Kinetics in HCV Clearance in Subjects With Hemophilia (HCV/Hemophilia)"

Sirs:

As of April 19, 2014, the ClinicalTrials.gov site indicates that this study is still recruiting:

"This study is currently recruiting participants. Verified October 2013 by University of Cincinnati

Sponsor: Kenneth Sherman
Collaborators: National Heart, Lung, and Blood Institute (NHLBI), Vertex Pharmaceuticals Incorporated ,Genentech

ClinicalTrials.gov Identifier: NCT01704521″

It should not be.

When the study was approved, it ran at the margins of ethically acceptable risk/benefit outcomes. Since then better alternative treatments have become available, while several reports indicate that the study procedure has higher risk and lower benefit than believed at the time of approval.

Relevant facts include:

1. The study procedure involves combination therapy with pINF, RIBA and Telaprevir. Real world experience with this therapy shows that side effects are several times more common and more serious* than reported in preapproval studies. We,"People with Bleeding Disorders and HCV," recommended approval of this therapy at FDA public hearings. We would not recommend approval now.

2. The CUPIC study shows that almost half* of the patients with advanced liver disease experience serious adverse events from the trial procedure! The target population for the subject study is patients with Hemophilia and HCV. This study population is known to have unusually high levels of advanced liver disease.

3. The study procedure includes interferon therapy. At least one major independent review argues that any interferon-based therapy produces worse outcomes than no therapy**.

4. Better alternative therapies are now available now***. FDA approval is expected shortly for additional, probably even better, therapies.

Mark Antell (202/3218627), Paul Brayshaw, and John Reed, for People with Bleeding Disorders and HCV

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* "A real-world study of recently approved hepatitis C protease inhibitors in the group of patients who have been told they should not wait for newer, experimental antivirals has shown a much higher rate of serious adverse events and treatment discontinuations than in clinical trials Just under half (48.6%) of patients receiving telaprevir experienced a serious adverse event, as did 38% of those treated with boceprevir. This high prevalence of serious side effects contrasted to rates of between 9% and 14% observed in the Phase 3 studies which led to the licensing of the drugs 'The safety profile of telaprevir or boceprevir with pegylated interferon/ribavirin in cirrhotic patients was poor,' commented the investigators."

Telaprevir and Boceprevir Effective but Cause Serious Side Effects in Patients With Cirrhosis, HIV and Hepatitis, April 2012

** "Most recently, another three trials that randomized patients with severe fibrosis (usually cirrhosis) into treatment arm (Peg-IFN) or no treatment have become available When the three

trails were put together using a widely-accepted statistical technique known as meta-analsis, the treatment did not provide any favorable clinically relevant benefits. In fact, when the two trials that were believed to be based on the best scientific methodology were considered, the recipients of the Peg-IFN had an increased mortality compared to the controls. While this could simply be a statistical chance event, it is the only information that we currently have and, at the very least, future patients who are going to be advised to have treatment with interferon-based combination therapy need to know about this observation as part of the informed consent process."
Hepatitis C treatment: no benefits and possible harm, R. L. Koretz – Medical News April 27, 2013.

*** see particularly FDA approval for Sovaldi and Olysio

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