Telaprevir for Hep C Study Open to People Living With HIV

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A clinical trial exploring the safety and effectiveness of Vertex Pharmaceutical's hepatitis C virus (HCV) protease inhibitor telaprevir in people also infected with HIV is open and enrolling patients, according to Vertex-verified report posted online by the National AIDS Treatment Advocacy Project (NATAP).

Standard treatment for HCV is a combination of two drugs—pegylated interferon and ribavirin—taken for 12 months. These drugs have significant side effects and work less well against HCV types 1 and 4, the most common strains in the United States, and even less well in HIV-positive people with one of those two HCV strains. Sustained virological response (SVR) rates—where a person's HCV levels in blood remain undetectable for at least six months after completing treatment—in people with HIV who have type 1 HCV are less than 30 percent.

Telaprevir is an inhibitor of HCV protease that works similarly to the HIV protease inhibitors now widely available. Vertex, collaborating with Tibotec and Mitsubishi, is evaluating its drug as part of a global Phase III program in more than 2,200 HCV treatment-naive and treatment-failure patients.

Phase I and II studies of telaprevir have shown promise in HCV-monoinfected patients—people infected with only HCV. In turn, there has been a great deal of interest in evaluating the therapeutic potential of the drug in people coinfected with both viruses.

A long-awaited clinical trial for people living with both HCV and HIV is now under way. Its purpose is to determine whether the combination of telaprevir with pegylated interferon and ribavirin is safe and effective in coinfected patients starting HCV treatment for the first time.

The study will enroll 68 HIV/HCV-positive people with an estimated completion date of June 2012.

All potential study volunteers must have HCV genotype 1 and have been living with HIV for at least six months. Patients must also have documentation of a liver biopsy within one year before screening for the study showing HCV-related inflammation and/or scarring (fibrosis).

Coinfected individuals who have previously undergone treatment with any approved or investigational drug or drug regimen for HCV will be excluded from the study.

The clinical trial is being conducted at sites in Baltimore, Chicago, Boston, New York City, Cincinnati and Dallas as well as Miami and Orlando in Florida and Beverly Hills, La Jolla and San Francisco in California.

People interested in screening for this study are encouraged to contact Vertex at 877-634-VRTX or medicalinfo@vrtx.com.

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