# PILOT Study: Three-Month Interferon-Free Regimen Cures 9 of 11 Geno 1, IL-28B CC Hep C Patients

April 23, 2012

A 12-week, interferon-free combination of two experimental, once-daily drugs—ABT-450, a hepatitis C protease inhibitor that requires blood-level boosting with the HIV protease inhibitor Norvir, and ABT-072, an HCV non-nucleoside polymerase inhibitor plus ribavirin—cured nine of 11 (82 percent) first-time treatment takers with HCV genotype 1 and an IL-28B CC genotype, according to data presented Thursday, April 19, at the 47th Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona.

Initially, 10 of the 11 (91 percent) genotype 1 patients treated with Abbott's two experimental agents plus ribavirin were dubbed cured in that they maintained undetectable HCV viral loads for 24 weeks following completion of therapy. There was, however, a late relapse, occurring 36 weeks after treatment was completed, in one patient.

The small Phase II study, dubbed PILOT, was reported at EASL by Eric Lawitz, MD, of Alamo Medical Research in San Antonio, Texas, and his colleagues. The 11 study volunteers, all with genotype 1 HCV and starting therapy for the first time, received 12 weeks of Norvir-boosted ABT-450, ABT-072 and weight-based ribavirin and were then followed for 48 weeks after completing treatment.

Usually, people are considered cured if their HCV remains undetectable for 24 weeks after finishing treatment, an outcome known as sustained virologic response, or SVR 24. Post-treatment follow-up was extended in this study because of concerns about late relapse with interferon-free regimens.

Because of the experimental nature of all-oral regimens, the study only included people with the IL-28B CC genotype—which is the most likely to be cured using interferon-based regimens—and who did not have cirrhosis or any contraindications to interferon-inclusive treatment. These were safeguards put into place by the researchers, in the event the regimen being used in the trial didn't work and patients needed to be switched to a regimen containing pegylated interferon.

Of the 11 study participants, the average age was 54; most were male (72 percent, or 8 of 11) and white (81 percent, or 9 of 11), and most had HCV genotype 1a (72 percent, or 8 of 11).

The drug combo worked quickly. By week four, HCV levels in all participants were undetectable, and they remained that way through week 12 of therapy.

One person relapsed eight weeks after treatment, and another at 36 weeks after treatment. In both cases, there was no evidence of pre-treatment drug resistance. However, after relapse, resistance to both protease and polymerase inhibitors was found in the person who experienced relapse at week eight, and polymerase resistance was found in the person who relapsed at week 36, Lawitz and his colleagues noted.

Although no additional relapses occurred by 48 weeks after treatment completion, the single late relapse may increase concerns about how long people should be followed after all-oral, interferon-free regimens before they are considered cured. Lawitz and his team reported that Abbott is currently analyzing data to determine whether the late relapse could have actually been a case of reinfection.

Although all participants experienced side effects, they were generally mild to moderate. Headache was most common, occurring in four people; there were three cases each of dry skin and nausea, and two cases of rash and acid reflux. There were no study discontinuations.

Laboratory abnormalities included two cases of indirect bilirubin elevations—without increases in other liver enzyme levels that indicate liver toxicity—which began after the first week of treatment and resolved during treatment. There was also a case of elevated blood glucose in a person with pre-existing diabetes.

Researchers at EASL also presented data from COPILOT, an interferon-free clinical trial combining ribavirin, Norvir-boosted ABT-450 and ABT-333, a twice-daily non-nucleoside polymerase inhibitor in first time-treatment takers and null responders with HCV genotype 1.

In conclusion, Lawitz and his study team underscored that PILOT is the first clinical trial to document a cure in more than 80 percent of people living with genotype 1 HCV using an interferon-free regimen for just 12 weeks. Ongoing trials pairing ABT-450/r with one or more direct-acting antiviral drugs, with or without ribavirin, are under way.

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