Simeprevir-based therapy offers cost-effective alternative in treatment of hepatitis C

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Researchers at Penn Medicine, in collaboration with a multi-center international team, have shown that a protease inhibitor, simeprevir, a once a day pill, along with interferon and ribavirin has proven as effective in treating chronic Hepatitis C virus infection (HCV) as telaprevir with interferon and ribavirin, the standard of care in developing countries. Further, simeprevir proved to be simpler for patients and had fewer adverse events. The complete study is now available online and is scheduled to publish in January 2015 in *The Lancet Infectious Diseases*.

"The observations from the study present simeprevir, peginterferon and ribavirin as a good therapeutic option for regions of the world where all-oral therapies are unavailable or cost prohibitive," says Rajender Reddy, MD, professor of Medicine and director of Hepatology the Perelman School of Medicine at the University of Pennsylvania. "This is the only study we are aware of that directly compares telaprevir to simeprevir." Telaprevir, another protease inhibitor, is an oral HCV medication taken up to three times daily, has multiple side effects and is less accessible than simeprevir. Simeprevir is manufactured by Janssen Pharmaceuticals.

In the U.S. and other countries where access to the latest research and treatment for HCV is available, physicians have moved towards all-oral therapy and away from interferon-based therapies such as these, as they are known to come with a significant number of side effects and are not as effective.

This Phase 3 randomized, double-blind study included 763 adults with chronic HCV genotype 1 infection, a form of the virus found in up to 75 percent of infections, and compensated liver diseases, who had previously not responded or only partially responded to at least one course of peginterferon and ribavirin.

Patients were randomized to receive simeprevir plus telaprevir placebo (379) or telaprevir plus simeprevir placebo (384) in combination with peginterferon and ribavirin for 12 weeks followed by 36 weeks of peginterferon and ribavirin alone.

The regimen of simeprevir with peginterferon and ribavirin proved to be as good as telaprevir and peginterferon and ribavirin, with 54 percent of patients in the simeprevir group versus 55 percent in the telaprevir group achieving a sustained virologic response (SVR), a lowering of the amount of virus in the body, 12 weeks after cessation of therapy. In prior partial responders, SVR was achieved in 70 percent versus 68 percent and in 44 percent versus 46 percent of previous non-responders following treatment with simeprevir and peginterferon and ribavirin and telaprevir and peginterferon and ribavirin treatment, respectively.

Sixty-nine percent of patients experienced simeprevir-related adverse events while 86 percent in the telaprevir group reported telaprevir-related adverse events.

"HCV treatment has been a moving target, especially for those who do not have access to or the ability to pay for the latest treatment options," says Reddy. "With this study, we showed that simeprevir once a day was well-tolerated in genotype 1 infected previous non-responders, making it a viable alternative to telaprevir for a segment of patients with HCV."

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