Interferon-free Hepatitis C Treatment for those Who Cannot Wait

April 22, 2014 By Lucinda K. Porter RN

Hepatitis C treatment is radically changing. Recently approved hepatitis C drugs along with those in the drug development pipeline, are dominating viral hepatitis news. In October 2014, a combination pill of sofosbuvir and ledipasvir is expected to be approved by the U.S. Food and Drug Administration (FDA) for hepatitis C genotype 1 patients. Translated, this combination drug formulated as a single pill is capable of curing 93-100% of most hepatitis C cases without interferon or ribavirin. It does this in a mere 8 to 12 weeks, and with mild side effects.

October is just around the corner for most of us, but for those with advanced liver disease, October may seem like an eternity. Those with early cirrhosis, hoping to stall further deterioration don't have the luxury of time. Fortunately, there are options for these patients, most notably, using both simeprevir (*Olysio*) and sofosbuvir (*Solvadi*).

In *Recommendations for Testing, Managing, and Treating Hepatitis C*, the American Association for the Study of Liver Diseases and the Infectious Diseases Society endorsed using simeprevir and sofosbuvir together for patients with genotype 1 who are unable to take interferon and for retreatment for certain patients with genotype 1. The EASL Hepatitis C recommendations are similar, "Patients with decompensated cirrhosis who are on the transplant list should be considered for IFN-free, ideally ribavirin-free therapy." (Note that patients in Europe have access to additional hepatitis C drugs, and the EASL recommendations aren't necessarily a specific endorsement of simeprevir and sofosbuvir.)

What sorts of results can hepatitis C patients hope for with these two drugs? At the 2014 International Liver Congress, Eric Lawitz and colleagues' presentation, "Simeprevir plus sofosbuvir with/without ribavirin in HCV genotype-1 prior null-responder/treatment-naÃ¨ve patients" (COSMOS study) gives us this information. Patients with advanced liver disease (METAVIR F3-4) receiving daily simeprevir and sofosbuvir had a 93-100% sustained viral response (SVR) at 12 weeks post-treatment. Patients treated for 12 weeks had 93% SVRs; patients treated for 24 weeks had 100% SVRs. Simeprevir and sofosbuvir worked well even in patients who typically might be difficult to treat with older hepatitis C drug regimens.

Simeprevir and sofosbuvir cannot be used in patients with the most advanced liver disease, i.e.

Child-Pugh B or C. Simeprevir and sofosbuvir are generally safe and well-tolerated. The most common side effects are fatigue, headache, and nausea. Simeprevir is an NS3/4A protease inhibitor. Sofosbuvir is a nucleotide analogue NS5B polymerase inhibitor. Together, they are a miracle, albeit an expensive one. Twelve weeks of this cocktail costs about $150,000. Most insurance companies are approving this combination of drugs, although often the approval comes after an appeal. The drug manufacturers offer prescription assistance to help with the approval and payment process.

For those needing prescription assistance, contact, Janssen (*Olysio*) and Gilead (*Sovaldi*).

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