New Hepatitis C Drugs Rolling Out Faster than Ever

April 29, 2014 By Lucinda K. Porter RN

I have been working in the hepatitis C field since 1997, and never have seen such an explosion of new drugs. At the end of 2013, the Food and Drug Administration (FDA) approved two new drugs to treat hepatitis C: *Olysio* (simeprevir) and *Sovaldi* (sofosbuvir). Solvadi's approval was especially exciting because it was the first all-oral treatment for hepatitis C. The FDA approved the all oral application for genotypes 2 and 3, but technically Sovaldi may be prescribed *off-label* without the use of interferon. Some physicians are using *Olysio* (simeprevir) and *Sovaldi* (sofosbuvir) together for patients with advanced liver disease, a combination that is turning out to be quite successful most of the time.

We have even more hepatitis C drugs just around the corner. Gilead submitted a new hepatitis C drug application to the FDA. Using a combination pill of sofosbuvir and ledipasvir, it is expected to be approved in October 2014 for hepatitis C genotype 1 patients. 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.

AbbVie is just behind Gilead in getting a hepatitis C drug regimen to market. Also expected to launch at the end of 2014, the AbbVie regimen will also be interferon/ribavirin free, and for genotype 1 patients. The response rates are 99% with similar, tolerable side effects.

Bristol-Myers Squibb also submitted new drug applications to the FDA for daclatasvir (an NS5A replication complex inhibitor) and asunaprevir (an NS3 protease inhibitor). The application request is for the treatment of hepatitis C in multiple genotypes. Daclatasvir amd asunaprevir have high response rates and mild to moderate side effects. If this combination is approved for genotypes 2, 3, and 4, it will compete with Sovaldi and ribavirin.

But that is not all. In 2015, there will be more hepatitis C drugs, giving patients more than ever to choose from.

Jules Levin of the National AIDS Treatment Advocacy Project (NATAP), the premier source of hepatitis C data, wrote, "I have been working in HCV since 1998...and this is the beginning of the new treatment era; we have been waiting for this for a long time."

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