The Wait for New Hepatitis C Drugs is Almost Over

April 8, 2014 By Lucinda K. Porter RN

Hepatitis C treatment is rapidly improving, and about to launch to a new dimension. To appreciate this, here is a brief history: My first hepatitis C treatment had a low cure rate. I had to give myself daily injections and endure horrendous side effects. My second hepatitis C treatment lasted for 48 weeks. The side effects were tough, but with weekly injections and a 50% cure rate, I thought I was getting a good deal. Unfortunately, it didn't work.

My third and thankfully last hepatitis C treatment was the easiest. I participated in a 12-week clinical trial using sofosbuvir, ledipasvir, and ribavirin. Although this was much easier than the two previous hepatitis C treatments, it was not without challenges. The rash and headache were easy to deal with. Sleep was impossible without the aid of modern chemistry. I was fatigued; my head was cloudy, and I was "difficult to be around."

I am not complaining about the last treatment; I am just stating my experience. It was worth it, because not only am I cured, but I feel better than I have in as long as I can remember. I lived with genotype 1a hepatitis C for 25 years, and now I am free. However, most of the people in the study are also free of hepatitis C, and they achieved this WITHOUT RIBAVIRIN, and thus with minimal side effects.

In approximately six months, the treatment I used in the clinical trial (without ribavirin) will likely be approved and available.

Here is the scoop: The U.S. Food and Drug Administration (FDA) granted priority review to Gilead Sciences for a once-daily pill combining ledipasvir and sofosbuvir (Sovaldi) to treat adults with genotype 1 chronic hepatitis C infection. Approval is expected by October 10, 2014.

What we know:

- In clinical trials (ION studies) of approximately 2,000 patients, the cure rates were around 94% and better for 8 to 12 weeks of treatment with ledipasvir and sofosbuvir.
- Patients reported mild side effects using ledipasvir and sofosbuvir; fatigue and headache were the most common adverse events.

What we don't know:

- If the FDA will approve the combination of ledipasvir and sofosbuvir for 8 or for 12 weeks.
- The cost. Solvadi’s $84,000 price tag is still the subject of public outcry. One can only imagine what this new combination pill will cost.
- The trade name. Ledipasvir is harder to say than sofosbuvir. Lovaldi anyone?

These are exciting times. If 25 years ago, someone said to me that hepatitis C would be cured with a pill taken daily for 8 to 12 weeks, I wouldn’t have believed it. Now not only do I believe it, I am living proof.

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