A Bright Future for Hepatitis C Patients

October 29, 2013 By Lucinda K. Porter RN

Recently, a panel unanimously recommended two new hepatitis C drugs for FDA approval. These panel recommendations will be reviewed next month and recommendations are expected by early December 2013. Here is a summary of where we are and where we are headed.

The first drug that was recommended is Johnson and Johnson's (Janssen) simeprevir, a protease inhibitor. Simeprevir is for genotype 1 patients only. It is used with peginterferon and ribavirin for 12 weeks, and then the patient continues with peginterferon and ribavirin.

Pros

- Shorter treatment length for treatment-naÃ¯ve and responder-relapsers at 24 weeks (12 weeks on triple therapy/12 weeks on peginterferon/ribavirin)
- Simeprevir has an easy treatment regimen with one daily pill plus peginterferon and ribavirin
- Can take pill with any food, not necessary to eat high-fat diet
- Higher response rates for prior non-responders than for other HCV treatments. However, recommendation for this group is for a 48-week treatment
- Overall, response rates are at least the same or better for everyone in the study except patients with Q80K (see next section)

Cons

- Genotype 1a patients have a high risk of a hepatitis C genetic variation known as Q80K, making them no more likely to respond to simeprevir than to placebo. Testing genotype 1a patients for Q80K will allow patients to pursue alternatives if they test positive for Q80K
- Adverse Events - These are troubling, with severe rash and photosensivity (sunburn) being the most pronounced. Patients of East Asian ancestry were at higher risk for severe side effects
- Still using peginterferon and ribavirin

The second drug that was recommended is Gilead's sofosbuvir, a polymerase inhibitor. There are two different applications:

Sofosbuvir in combination with peginterferon and ribavirin for **treatment-naÃ¯ve adults** with **genotype 1 or 4**

Pros

- Short 12-week treatment duration, with limited exposure to peginterferon and ribavirin
- High cure rate at around 90%
- Easier to tolerate side effect profile
- Sofosbuvir is once daily pill
- Highest rate of response in Blacks
- Low drug-resistance profile

Cons

- Treatment may not be approved for genotype 5 or 6 yet
- Still uses peginterferon and ribavirin
- May not yet be approved for previously-treatment hepatitis C patients

Sofosbuvir with ribavirin for the treatment of adults with genotypes 2 or 3. Unsure if the treatment length will be 12 or 16 weeks. Extending the treatment duration by 4 weeks increased SVR12 rates in genotype 2 subjects from 82% to 89%, and in genotype 3 subjects from 30% to 62%.

Pros

- If approved, this will be the first all-oral hepatitis C treatment
- No interferon
- Short treatment duration, with limited exposure to ribavirin
- High cure rate for genotype 2 patients at 82-89%
- Easier to tolerate side effect profile
- Sofosbuvir is once daily pill

- Low drug-resistance profile
- May be approved for previously-treatment genotype 2 or 3 hepatitis C patients

Cons

- Response rates for genotype 3 patients are not as high as they would be if peginterferon plus ribavirin are used. Patients with genotype 3 will need to decide between 24 weeks of peginterferon and ribavirin at 82% response rates versus 12 weeks of sofosbuvir and ribavirin at 62%.
- Still uses ribavirin

What's Ahead

In 2014 we expect two new interferon-free regimens to be approved:

- Abbvie's ABT450 plus ABT267 plus ABT333 (not sure if this will be with or without ribavirin) In phase 2 the Abbvie regimen had 97% SVR rates with 12 weeks therapy
- Gilead's sofosbuvir ledipasvir (not sure if this will be with or without ribavirin) In phase 2 the Gilead regimen had 95-100% SVR with 12 weeks therapy

Additionally, the FDA granted "Breakthrough Therapy Designation" to Merck for MK-5172/MK-8742, an oral combination regimen. In short, the future looks bright for hepatitis C patients.

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