Hepatitis C Treatment: The Race Is On

September 10, 2014 By Lucinda K. Porter RN

Hepatitis C patients who are waiting for new antiviral therapies take note: **hepatitis C treatment is changing quickly**. A month from now, the Food and Drug Administration (FDA) is expected to approve Gilead Sciences' once-daily pill for adults with genotype 1 chronic hepatitis C infection. The pill combines ledipasvir and sofosbuvir (Sovaldi) with cure rates of better than 90% after 8 to 12 weeks of treatment. The side effects are generally mild.

Here is what we don't know yet:

- If the FDA will approve the ledipasvir/sofosbuvir combo for 8 or 12 weeks
- If the FDA will approve the combo with or without ribavirin (I think it will be without ribavirin.)
- The name of the combo pill (I think it will be a three-syllable word that sounds like an opera or a car model.)
- The cost of the pill (One of the ingredients, sofosbuvir is $1000 per pill, so I am guessing that the total treatment cost will exceed the price of a luxury automobile.)

The pill isn't even out now, and hepatitis C patients want to know what's next. Genotype 3 hepatitis C patients are especially curious, since they are now saddled with the hardest to treat genotype. Here is a micro-encapsulation of what I anticipate:

Genotype 1

Sofosbuvir (Sovaldi) + asunaprevir (Sunvepra) by Bristol-Myers Squibb (Gilead owns Sovaldi) - Limited data. Reported cure rates ranging from 80% to 90% with 12 and 24 weeks of therapy in a variety of patients (naÃ¨ve and prior non-repsonders). Mild to moderate side effects. Approval expected late 2014.

ABT450r + ABT267 + ABT333 (with or without ribavirin) by AbbVie - The SAPPHIRE, TURQUOISE and PEARL studies reported cure rates ranging from 89% to 100% with 12 weeks of therapy. The side effects were generally mild, depending on whether ribavirin was used. The big drawback with this regimen is the number of pills. However, if the cost is right, it is worth considering. Approval expected late 2014.

MK-5172 + MK-8742 (with or without ribavirin) by Merck - The C-WORTHY studies reported cure rates ranging from 90% to 100% with 12 weeks of therapy. The side effects were generally mild, depending on whether ribavirin was used. Approval expected 2015.

Sovaldi (sofosbuvir) + daclatasvir (with or without ribavirin) by Bristol-Myers Squibb (with Gilead's Sovaldi) - Study in *New England Journal of Medicine* reported cure rates ranging from 92% to 100% with 12 weeks of therapy. The side effects were generally mild, depending on whether ribavirin was used. Approval expected in 2015.

Studies are underway looking at 4 and 6-week durations using various combinations of antiviral drugs.

Genotype 2 and 3

Sovaldi (sofosbuvir) + daclatasvir + ribavirin - Small treatment-naÃ¯ve study - 89% SVR

Sovaldi (sofosbuvir) + GS 5816 - Small treatment-naÃ¯ve study - 93% SVR

Genotypes 1 through 6

Sovaldi (sofosbuvir) + GS 5816 - Gilead Sciences - ELECTRON study reported cure rates around 95% with 12 weeks of therapy. The side effects were generally mild. Perhaps a 2015 approval.

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