The Next HCV Drugs

Information about hepatitis C drugs that are in the pipeline. This article originally appeared in the HCV Advocate

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The current standard of care for treating HCV is currently Harvoni and Viekira PAK for genotype 1, Sovaldi plus ribavirin to treat genotype 2 and 3, and Sovaldi plus pegylated interferon/ribavirin to treat genotype 4. There are a couple of combinations of drugs submitted to, and likely to be approved by, the Food and Drug Administration (FDA) by the end of this year or early next year. Additionally, many more drugs are being developed that are in early to mid-stage development. These medications hold the promise to cure even more people with HCV genotypes 1 through 6. This month I discuss the most promising drugs in development.

Merck: Grazoprevir/Elbasvir (one pill/once-a-day) in treatment-naïve and treatment-experienced patients infected with HCV genotype 1, 4 or 6 and treated for 12 weeks. The cure rates were up to 100%. There were issues with NS5A resistance, but Merck is conducting more clinical trials with NS5A inhibitors to overcome this problem. Merck has filed a New Drug Application earlier this year. Merck was awarded Breakthrough Therapy Designation by the FDA for genotype 4 and to treat those with severe kidney disease—the studies above included patients with genotype 4 and severe kidney problems. FDA approval is expected by year end.

Bristol-Myers Squibb (BMS): BMS has two drug combinations that are being tested to treat hepatitis C.

- **Ally-1**: Daclatasvir plus sofosbuvir has been awarded Breakthrough Therapy Designation for patients with advanced cirrhosis and those with HCV genotype 1 with HCV post-liver transplant. In the Ally-1 study, the cure rates of the patients with advanced cirrhosis were 82% for genotypes 1 and 94% for the post-patients with genotype 1.
- **Ally-3**: BMS has completed their phase 3 clinical trials of daclatasvir plus sofosbuvir and submitted their data to the FDA for approval. (Note: Since this article was wrtten, daclatasvir was approved under the name Daklinza). In the trials, treatment naïve people treated for 12 weeks with the combination of daclatasvir/sofosbuvir achieved cure rates of 90%, and 86% in

people who are treatment experienced. In people who did not have cirrhosis, the cure rates were 96%. These are very high cure rates.

BMS also has a fixed-dose single-pill regime (daclatasvir, asunaprevir, beclabuvir) to treat HCV genotype 1a and 1b that is taken twice daily for 12 weeks. There were two separate studies that included treatment naïve and treatment experienced patients with and without cirrhosis. The studies also included arms with and without ribavirin. The overall cure rates were up to 98% with ribavirin and 93% without ribavirin. Breaking it down by subtype—genotype 1b had approximately 10% higher cure rates than genotype 1a. The cure rates observed in the ribavirin groups were not statistically higher.

The second single-pill combination listed above hasn't been submitted to the FDA but it is expected to be submitted soon, and approval is expected mid-2016.

Gilead: Sofosbuvir plus GS-5816 with and without ribavirin. In a phase 2 study of 104 genotype 3 patients treated for eight weeks the cure rates were up to 100%. GS-5816 is active against genotypes 1-6 (pangenotypic). It is listed in www.clinicaltrials.gov as a phase 3 trial that is active but not recruiting. The phase 3 study will be a fixed dose of one pill with both drugs given once a day to treat genotypes 1 through 6. The treatment duration will be either 8 or 12 weeks.

Janssen: Olysio made a big splash last year as a combination with sofosbuvir with major prescriptions and high cure rates. They have acquired Vertex's HCV drugs in development (ALS-2200). This year Janssen signed an agreement to codevelop and commercialize Achillion's inhibitors (ACH-3102, ACH-3422 and sovaprevir). Although no data is available, it should make for a very interesting 2015-2016. If I can steal a common term, they seem to have a very robust pipeline. As listed above, Janssen many opportunities to develop and commercialize HCV drugs for the short term and long term. Keep on eye on Janssen.

AbbVie: In cooperation with Enanta, AbbVie is testing ABT-493, plus ABT-530 with and without ribavirin to treat genotypes 1 through 6 for 8 to 12 weeks. The drugs are in phase 2 studies.

The Merck approval is expected soon. The BMS plus sofosbuvir is also expected to be approved soon. (Approved since this article went to press.) The new Gilead drugs are likely to be approved by next year and will be followed by the second BMS combination, Janssen's combinations, and AbbVie's. Hopefully, more agents will be discovered that will show even more promise, and we just may have a market that is flooded with excellent drugs that will work for everyone.

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