What's Next in the Hepatitis C Treatment Pipeline?

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Recently, the Food and Drug Administration (FDA) granted breakthrough therapy designation to AbbVie's experimental hepatitis C regimen glecaprevir (ABT-493)/pibrentasvir (ABT-530). Abbreviated G/P, this two-drug combo is being tested for the treatment of chronic hepatitis C in persons with genotype 1 who failed previous therapy with direct-acting antivirals (DAAs), including therapy with an NS5A inhibitor and/or protease inhibitor.

What is breakthrough therapy designation?

According to the FDA, "Breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy." When an experimental treatment is given the breakthrough therapy designation, the road to FDA-approval includes an accelerated, priority review.

What do we know about glecaprevir and pibrentasvir?

Also known as ABT-493 and ABT-530, glecaprevir (ABT-493) is an NS3/4A protease inhibitor, while pibrentasvir (ABT-530) is an NS5A inhibitor. The combination glecaprevir/pibrentasvir is being tested for the treatment of chronic hepatitis C infection in adults for genotypes 1 through 6. Clinical trials are comparing results for people with hepatitis C after eight versus 12 weeks, as well as for people with severe kidney disease, with and without cirrhosis.

Results from the small MAGELLAN-1 study presented at the 2016 EASL meeting were encouraging. Two patients out of a total of 22 experienced virologic failure, and no subjects discontinued treatment because of adverse events. The most common adverse events were headache, fatigue and nausea.

What does this mean for people with hepatitis C?

At this point, it is too soon to know. G/P extends hope to people who failed prior treatments. Along with shorter treatment lengths and the potential to treat people with chronic kidney disease, the AbbVie regimen is one to watch.

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