Merck’s Newest Hepatitis C Antivirals

November 16, 2016 By Lucinda K. Porter RN

At this year’s Liver Meeting in Boston, there were seven presentations using Merck’s experimental and approved hepatitis C (HCV) direct-acting antivirals (DAAs). The data are looking quite good at this point. I will summarize two.

Note that conference presentations are preliminary investigations, and need to be published in a peer-reviewed journal before data can be considered conclusive.

Abstract #110 Safety and Efficacy of the Fixed-Dose Combination Regimen of MK-3682/Grazoprevir/MK-8408 With or Without Ribavirin in Non-cirrhotic or Cirrhotic Patients with Chronic HCV GT1, 2 or 3 Infection (Part B of C-CREST-1 & 2) - Eric Lawitz, et al.

This Phase 2 study enrolled 603 subjects. The study design was complicated, using multiple arms, varying treatment durations, and pretty much every scenario was tested (gentoypes 1,2,3; HCV monoinfection or HIV/HCV coinfection, cirrhosis or not, naïve or prior treatment). The test drugs were once daily MK-3682 (NS5B uridine nucleotide polymerase inhibitor), grazoprevir (GZR, NS3/4A protease inhibitor), and MK-8408 (next generation NS5A inhibitor).

Treatment was generally well tolerated, and the most common complaints were fatigue, headache, and nausea. A subject died from a cause unrelated to the study drug (bacterial sepsis).

The bottom line is high response rates to treatment, regardless of what factors were at play. Eight weeks of treatment with MK-3682B resulted in SVR12 rates of 95 percent in GT1, 86 percent in GT2 and 95 percent in GT3 subjects. The 12-week treatment arm did better with 99 percent in GT1, 97 percent in GT2, and 97 percent in GT3. Cirrhotic and noncirrhotics had comparable response rates. All GT1 and GT2 subjects who received 12 weeks of MK-3682B were cured (SVR12).

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Abstract #193 Safety and Efficacy of the Fixed-Dose Combination Regimen of MK-3682/Grazoprevir/MK-8408 in Cirrhotic or Non-cirrhotic Patients with Chronic HCV GT1 Infection who Previously Failed a Direct-acting Antiviral Regimen (C-SURGE) - David L. Wyles, et al.

Patients who have failed treatment containing a direct-acting antiviral (DAA) regimen using Harvoni (ledipasvir/sofosbuvir) or Zepatier (elbasvir/grazoprevir) need retreatment options. This multicenter study tested MK-3682 (NS5B polymerase inhibitor)/grazoprevir (NS3/4A protease

inhibitor) and MK-8408 (NS5A inhibitor) in subjects who failed a previous DAA regimen. All 94 subjects had genotype 1 and 42 had compensated cirrhosis. Treatment was generally well tolerated and no one discontinued the study due to an adverse event.

The bottom line is that this study is still in progress, with excellent results. So far, Merck has hit a home run with these data. However, the study is still in progress, and the question is, will this be a grand slam? Keep posted for updates, particularly in the spring.

There were other equally exciting presentations for patients looking for retreatment options. We have come a long way from the old days of peginterferon and ribavirin. Thank goodness.

For more news from the 2016 Liver Meeting, check out HEP's newsfeed.
