Hep C News: Study for Hep C Treatment Drugs, Daclatasvir with Sovaldi for Genotype 3

May 27, 2015 By Connie M. Welch

A clinical study using new hep C treatment drugs by Bristol Myers, daclatasvir with Sovaldi for hep C patients with genotype 3, shows high cure rate results. Genotype 3 is one of the hard to treat hep C genotypes.

The recent study was reported at the 50th International Liver Congress in Vienna, Austria in April 2015. Researchers from the French Compassionate Use Program reported the interim analysis for the study targeting genotype 3 patients with and without cirrhosis.

The study consisted of 601 patients:

- All patients over 18 years
- Majority of patients in this study had advanced fibrosis or cirrhosis (77%) and (73%) patients failed a previous hep C treatment
- Some patients had extra-hepatic manifestations meaning they had other medical conditions not in the liver
- Some patients had post-liver transplant hep C recurrence
- Some patients had indications for need for liver or kidney transplant
- 64% to 15% of patients were scheduled to receive daclatasvir and Sovaldi for 24 weeks with or without ribavirin, respectively
- 4% to 17% of patients were scheduled to receive daclatasvir and Sovaldi for 12 weeks with or without ribavirin, respectively

All patients received hep C drugs daclatasvir and Sovaldi once daily for 12 or 24 weeks. Ribavirin was added at the physicians discretion. RNA viral load test was done for baseline and at post treatment weeks 4 and 12.

The background notes reported:

- Treatment options for hep C genotype 3 patients are limited
- The combination daclatasvir and sovaldi for 12 weeks showed high SVR rates (sustained virologic response, meaning the hep C virus is non-detected for the weeks listed)in non-cirrhotic patients (96% SVR12) and lower response in cirrhotic patients (63% SVR12)
- Genotype 3 patients with cirrhosis remain difficult to treat and may benefit from the addition of ribavirin or extended treatment duration

Daclatasvir (DCV) is a:

- Pangenotypic NS5A inhibitor, low potential for drug to drug interactions
- Safe and well tolerated
- Studied in >13,000 patients
- Approved in Japan, Europe, and Brazil; currently under US regulatory review

Sofosbuvir (SOF or Sovaldi) is a:

- Pangenotypic nucleotide NS5B inhibitor, low potential for drug to drug interaction
- Safe and well tolerated
- Approved in combination with other hep C agents in US, Europe and Canada

Conclusions from this study showed the preliminary analysis is consistent with previous findings and demonstrates 12 weeks of daclatasvir and Sovaldi for genotype 3 non-cirrhotic patients resulted in high SVR4 rates. Cirrhotic patients appeared to benefit from extended treatment duration of 24 weeks. See Conference reports for NATAP/reported by Jules Levin/EASL 2015 April 22-26 Vienna Austria.

More news will be reported about daclatasvir and Sovaldi as clinical studies release data. Continued work is in progress for a variety of hep C genotypes with varying liver conditions.

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