# Hep C News: FDA Approves Bristol Myers Squibb New Treatment for Hep C Genotype 3 with Daklinza (Daclastavir)

September 9, 2015 By Connie M. Welch

---

The FDA approved a new treatment for Hep C Genotype 3, Daklinza (daclatasvir) on July 24, 2015. Bristol Myers Squibb's (BMS) Daklinza is to be used in combination with sofosbuvir, without the need for interferon or ribavirin.

Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research stated in the FDA news release, "Today's approval provides a new option for patients with genotype 3 HCV, including those patients who cannot tolerate ribavirin."

This is the first treatment for Hep C specifically approved for genotype 3 without the need for interferon or ribavirin for 12 weeks. Up to now, Hep C treatment for genotype 3 has consisted of combination treatment using Sovaldi (sofosbuvir), and ribavirin for 24 weeks or Sovaldi (sofosbuvir), Interferon and ribavirin for 12 weeks, which brought more side effects.

Genotype 3 is the second most common genotype in the United States, with Genotype 1 being the most prevalent type, which makes up 70 percent of those infected with HCV in the United States.

Daklinza (daclatasvir) combined with sofosbuvir, is a once daily regimen for 12 weeks. FDA reported, the safety and efficacy of Daklinza in combination with sofosbuvir were evaluated in a clinical trial of 152 treatment-naive and treatment-experienced participants with chronic HCV genotype 3 infection.

Participants received Daklinza 60 mg plus sofosbuvir 400 mg once daily for 12 weeks and were monitored for 24 weeks post treatment.

The safety and efficacy of Daklinza in combination with sofosbuvir were evaluated in a clinical trial of 152 treatment-naive and treatment-experienced participants with chronic HCV genotype 3 infection. Participants received Daklinza 60 mg plus sofosbuvir 400 mg once daily for 12 weeks and were monitored for 24 weeks post treatment. The studies were designed to measure whether a participant's hepatitis C virus was no longer detected in the blood 12 weeks after finishing treatment (sustained virologic response), suggesting a participant's infection had been cured.

Results showed cure rates; for 98 percent of the treatment-naive participants with no cirrhosis of the liver and 58 percent of the treatment-naive participants with cirrhosis achieved sustained virologic response. Of the participants who were treatment-experienced, 92 percent with no cirrhosis of the liver and 69 percent with cirrhosis achieved sustained virologic response.

Daklinza labeling carries a *Limitations of Use* statement to inform prescribers that sustained virologic response rates are reduced in HCV genotype 3 infected patients with cirrhosis.

Safety information was available for approximately 1,900 patients with HCV treated with the recommended dose of Daklinza in combination with other anti-HCV drugs in clinical trials. The most common side effects of Daklinza with sofosbuvir were fatigue and headache.

Cautions are reported when taking current medications with use of treatment. Daklinza carries a warning for patients and health care providers that serious slowing of the heart rate (symptomatic bradycardia) and cases requiring pacemaker intervention have been reported when amiodarone is co-administered with sofosbuvir in combination with another HCV direct-acting antiviral, including Daklinza. Co-administration of amiodarone with Daklinza in combination with sofosbuvir is not recommended.

Read more in the FDA press release about Daklinza's approval.
Dr. Joseph Galti M.D., a hepatologist with Liver Specialists of Texas in Houston, talks about Daklinza and the details of treatment in this video presentation.

*This entry was originally published on Life Beyond Hepatitis C, August 5, 2015. It is reprinted with permission.*

---