# 3-Drug Combo Halts HCV Infection

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WASHINGTON -- An investigational three-drug oral combination that avoids the use of both interferon and ribavirin allows a high percentage of patients infected with hepatitis C virus to achieve a sustained virologic response, researchers said here.

The 12-week sustained virologic response -- akin to remission from the infection -- was reached by 92.2% of patients treated with daclatasvir plus asunaprevir and a 75-mg twice-daily dose of BMS-791325, a new non-nucleoside agent; and a 12-week sustained virologic response was achieved by 91.7% of patients on the regimen that used a 150-mg twice-daily dose of BMS-791325, said Gregory Everson, MD, professor of medicine at the University of Colorado Anschutz Medical Campus, Aurora.

In his late-breaker oral presentation at the American Association for the Study of Liver Diseases, Everson said the efficacy of the treatment was observed in cirrhotic patients and in non-cirrhotic patients; in patients with genotype 1a and in genotype 1b, and in patients with favorable and unfavorable genetics.

"This was a well-tolerated regimen with low rates of adverse events and treatment discontinuation, regardless of the dose of BMS-791325," Everson said. There were three serious adverse events -- one among the 80 patients on the low-dose regimen and two among the 86 patients on the high dose, he said.

"These results support phase III trials with a twice-daily fixed-dose combination of daclatasvir/asunaprevir/BMS-791325 at the 75-mg dose level," he said. The treatment course was 12 weeks, followed by a 12-week observation period to determine if a sustained virologic response had been achieved.

In the phase IIb trial, researchers enrolled treatment-naïve patients, stratified by genotype 1a of genotype 1b and by presence of biopsy-confirmed cirrhosis. About 10% of cirrhotics were assigned to each group. The primary endpoint was sustained virologic response at 12 weeks by achieving the lower limit of assay quantification.

"The results in this trial look promising," said Michael Fried, MD, director of the University of North Carolina Liver Center in Chapel Hill. "But this was a phase IIb trial. We have to see what happens in the phase III studies."

In the study, researchers enrolled a predominantly male cohort (67%) which had a median age of 54 years. About 83% of the cohort was white; blacks or African Americans accounted for 16% of the group. About 82% of the patients were infected with hepatitis C virus genotype 1a. About 9% of the patients -- 15 individuals -- were diagnosed with cirrhosis.

At the end of treatment, Everson said that 97.5% of patients had responded to therapy in the low-dose group, and 94.2% had responded in the high-dose treatment cohort. The 4-week sustained virologic response was achieved by 92.4% of the low-dose patients and by 91.7% of the high-dose patients.

Virologic failure occurred in six patients on the low-dose regimen -- four patients relapsed before they had reached the 4-week sustained virologic response milestone. In the high-dose treatment group, five relapses occurred, three prior to the 4-week mark. No relapses occurred after 4 weeks, Everson noted.