BMS Drug Boosts Hep C Cure Rates

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Adding BMS-790052, an experimental hepatitis C drug being developed by Bristol-Myers Squibb, to pegylated interferon and ribavirin dramatically increased cure rates among first-time treatment takers with hepatitis C virus (HCV) genotype 1, according to a Phase IIa study presented at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), held September 17 to September 20, in Chicago. Overall, 83 percent of people treated with 48 weeks of 10 or 60 milligrams (mg) BMS 790052 once-daily plus pegylated interferon and ribavirin achieved sustained virologic results, versus 25 percent of the group who received pegylated interferon and ribavirin plus placebo.

Some of the traditional indicators of treatment outcome did not always predict response to treatment. For example, all of the 36 people treated with BMS-790052 plus pegylated interferon and ribavirin had more than a 99 percent drop in their hepatitis C viral load after 12 weeks of treatment. This is known as an early virologic response, or EVR, and is usually an excellent indicator that treatment is working and should be continued. In the study reported at ICAAC, however, only 25 people with EVRs were ultimately cured.

Conversely, viral “blips”—when hepatitis C virus temporarily re-appears at a low level during or after treatment—did not always predict treatment failure. Of the seven patients who experienced blips, four were ultimately cured.

BMS-790052 belongs a class of drugs called NS5a replication complex inhibitors. Naturally occurring mutations known as polymorphisms are known to confer resistance to this class of drugs. But Stanislaus Pol, MD, of the Hôpital Cochin in Paris and his colleagues noted that these polymorphisms did not prevent people from being cured. Of the 13 study participants who had evidence of NS5a-associated polymorphisms before starting treatment, 10 were cured. However, evidence of resistance to BMS-790052 was found in all of the 11 people whose hep C virus returned during treatment or who relapsed afterward.

BMS-790052 did not add to, or worsen, side effects from pegylated interferon and ribavirin. The investigators did not observe any increase in rash, liver-related side effects or laboratory abnormalities, with the addition of BMS 790052. However, the small size of this study—48 people total; 12 each in the 3 mg, 10 mg and 60 mg groups, and 12 in the placebo group—makes it is difficult to draw conclusions about side effects from BMS-790052; larger studies will be needed.

This trial was the first to test cure rates after triple therapy with an NS5a replication inhibitor. The

investigators noted that the results support further studies of BMS-790052, in combination with other oral antiviral HCV drugs, with or without pegylated interferon and ribavirin.

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