Interferon-Free Protease/Polymerase Inhibitor Combo Showing Well in Hep C Genotype 1 Study

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Boehringer Ingelheim has its eyes set on interferon-free treatment for genotype 1 hepatitis C virus (HCV) infection. The treatment combines two of its own drugs, the protease inhibitor BI 201335 and the polymerase inhibitor BI 207127, and encouraging results were reported Monday, November 7, at the 62nd annual meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco.

Though final results from the SOUND-C2 study are pending, early data suggest the combination of both drugs—when used with ribavirin—has pushed HCV viral loads undetectable in the majority of study volunteers after 12 weeks of treatment. What's more, according to the analysis presented by Stefan Zeuzem, MD, of the J.W. Goethe University Hospital in Frankfurt and his colleagues, the shortest treatment duration tested in the study—16 weeks of therapy—had 59 percent of participants maintaining undetectable HCV viral loads 12 weeks after completing treatment, a strong sign of ultimately being cured of the infection.

SOUND-C2 has enrolled 362 people living with genotype 1 HCV—all of whom were starting treatment for the first time—to receive 120 milligrams (mg) BI 201335 once daily, but with different dosing of BI 207127 (600 mg two- or three-times daily) and for different treatment durations (either 16, 28 or 40 weeks). In four of the five treatment groups, ribavirin is being given as a third drug. The fifth treatment group is receiving once-daily BI 201335 plus three-times-daily BI 207127 without ribavirin for 28 weeks.

All five treatment groups of the interferon-free oral combination showed high virologic response rates through week 12. Between 70 percent and 76 percent of study volunteers who received BI 201335, BI 207127 and ribavirin had undetectable HCV viral loads after 12 weeks of treatment, with 13 percent to 21 percent of patients developing a viral load breakthrough during treatment.

As for those who used the experimental protease inhibitor and polymerase inhibitor without ribavirin, 57 percent had viral loads below the level of detection after 12 weeks of treatment.

The sustained virologic response rate at 12 weeks post treatment (SVR12), which is considered highly predictive of cure of the infection, was achieved by 59 percent of the participants

randomized to the group receiving 16 weeks of therapy with once-daily BI 201335, three-times-daily BI 207127 and ribavirin.

Weakness, itching, rash, hypersensitivity to sun exposure, yellowing of the skin and eyes, nausea, vomiting and diarrhea were the most common side effects in the study, occurring in more than 25 percent of patients. Between 6 percent and 12 percent of volunteers have discontinued treatment because of side effects, with most dropouts occurring among those receiving once-daily BI 201335, three-times daily BI 207127 plus ribavirin.

“Interferon-free oral combination therapy with BI 201335, BI 207127 and ribavirin provides high virologic response rates in HCV genotype 1 patients starting therapy for the first time,” Zeuzem concluded, “confirming the potent antiviral activity of this combination. The response rate in the ribavirin-sparing arm was substantial but lower than in other arms at week 12.”

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