Novel Lambda Peg-Interferon Has Safety Edge Over Approved Peg-Interferon

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A novel version of interferon—pegylated interferon lambda-1a (peg-IFN-lambda)—combined with ribavirin cured up to three-quarters of people with genotype 2 or 3 hepatitis C virus (HCV) infection in the Phase II EMERGE trial conducted by Bristol-Myers Squibb (BMS), according to new data presented Thursday, April 19, at the 47th Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona.

Compared with a standard form of interferon—Pegasys (pegylated interferon alfa-2a)—peg-IFN-lambda was associated with fewer flu-like and musculoskeletal symptoms, along with lower rates of anemia and white blood cell and platelet decreases. Interferon and ribavirin dose reductions because of anemia were also less likely among those using BMS's experimental interferon formulation in the study.

Though the future of pegylated interferon as a component of treatment for HCV infection is unclear, given the proliferation of all-oral agents with promising results, it is widely believed that interferon-containing regimens may be necessary for some people living with hepatitis C in the foreseeable future. In turn, such people welcome the development of novel interferons that are both effective and associated with fewer side effects than approved pegylated interferon alfa formulations.

The EMERGE study is exploring the safety and efficacy of peg-IFN-lambda, an interferon formulation being developed by BMS that targets a receptor that is less widely distributed through the body than the receptor for pegylated interferon alpha and, thus, may have fewer systemic side effects. The study has enrolled 526 people living with genotypes 1, 2, 3 and 4 HCV infection starting therapy for the first time.

The data presented by Stefan Zeuzem, MD, of Goethe University Hospital in Frankfurt, Germany, and his colleagues at EASL focused on 118 patients with genotype 2 or 3 HCV infection who received either weekly Pegasys injections or one of three weekly doses of peg-IFN-lambda (240, 180 or 120 micrograms), all in combination with ribavirin, for 24 weeks.

Sustained virologic response rate data 24 weeks post-therapy (SVR 24) are available for the

genotype 2 and 3 HCV patients in EMERGE; SVR 24 results for people with genotype 1 and 4 HCV infection—who required up to 48 weeks of treatment—are pending.

In patients with genotypes 2 or 3 HCV, peg-IFN-lambda/RBV was associated with SVR 24 rates that were similar to those seen in patients treated with Pegasys/RBV. In the Pegasys group, the SVR 24 rate was 53.3 percent. Among those in the 250 microgram peg-IFN-lambda group, the SVR 24 rate was 60 percent. Among those in the 120 microgram group, the rate was 65.5 percent. And among those in the 180 microgram group, the SVR 24 rate was 75.9 percent.

It is the 180 microgram dose of peg-IFN-lambda that has been selected to be evaluated further in Phase III clinical trials.

Overall, the rates of serious side effects and other adverse events were similar in all treatment groups up to week 24 following completion of therapy.

There were, however, some important differences. Whereas flu-like symptoms (e.g., fever, chills and pain) occurred in roughly 17 to 23 percent of those in the peg-IFN-lambda groups, they were documented in 40 percent of those in the Pegasys group. Musculoskeletal symptoms (e.g., joint pain, muscle soreness and back pain) occurred in 17 to 28 percent of those receiving any dose of peg-IFN-lambda, compared with more than 63 percent of those treated with Pegasys. Fatigue, at least in the 180 microgram peg-IFN-lambda group, was roughly twice as less likely compared with those in the Pegasys group (28 versus 53 percent, respectively).

Psychiatric problems, including depression, irritability or insomnia, appeared to be more common among patients receiving peg-IFN-lambda, compared with those receiving Pegasys. In the 180 microgram peg-IFN-lambda group, psychiatric problems were documented in 41 percent of patients. In the Pegasys group, 33 percent of patients experienced psychiatric problems.

As for lab-based adverse events, severe neutropenia (decrease in bacteria-fighting white blood cells) didn’t occur in any patients treated with the 180 microgram dose of peg-IFN-lambda, compared with more than 27 percent of those in the Pegasys group. Severe anemia occurred in nearly 7 percent of those treated with 180 micrograms of peg-IFN-lambda, compared with nearly 45 percent of those in the Pegasys group. Severe thrombocytopenia (very low platelet counts) didn’t occur in any patients in the 180 microgram peg-IFN-lambda group, compared with nearly a quarter of patients in the Pegasys group.

About 7 percent of patients in the 180 microgram peg-IFN-lambda group required an interferon dose reduction because of side effects, compared with nearly 27 percent of those in the Pegasys group. Similarly, ribavirin dosing only needed to be reduced by 7 percent of those in the peg-IFN-lambda group, compared with more than 43 percent of patients in the Pegasys group. Nearly a quarter of those in the Pegasys group needed to reduce their ribavirin dose because of anemia, compared with none of the patients in the 180 microgram peg-IFN-lambda group.

In conclusion, Zeuzem and his colleagues note, “[Peg-IFN-lambda/RBV] was associated with a

comparable SVR 24 rate in patients with HCV genotype 2, 3 with fewer musculoskeletal and flu-like symptoms, less hematologic toxicity and fewer peg-interferon or RBV dose modifications versus [Pegasys/RBV].”

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