90% Geno 1 Patients Nearing Cure in 7977/Interferon Study

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Ninety percent of people with genotype 1 hepatitis C virus (HCV) starting therapy for the first time show a clear sign of being cured of their infection using a 12-week treatment regimen containing Gilead Sciences' nucleotide analogue GS-7977 plus pegylated interferon and ribavirin (peg-IFN/RBV), according to preliminary data from a Phase II clinical trial presented Thursday, April 19, at the 47th Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona.

The new results, highlighting 12-week sustained virologic response (SVR 12) rates involving one group of patients in the ATOMIC study, were presented by Kris Kowdley, MD, of the Virginia Mason Medical Center in Seattle and his colleagues. The study, which is ongoing, has enrolled 316 people with genotype 1 HCV infection to receive either 12 weeks of GS-7977 plus peg-IFN/RBV, 24 weeks of GS-7977 plus peg-IFN/RBV or 12 weeks of GS-7977 plus peg-IFN/RBV plus an additional 12 weeks of either GS-7977 alone or GS-7977 plus ribavirin (but not pegylated interferon). An additional 16 patients with genotypes 4 or 6 HCV infection are also enrolled in ATOMIC and will be receiving a 24-week course of GS-7977 plus peg-IFN/RBV.

SVR 12 data are only available for the 52 patients in the first group, treated with GS-7977 plus peg-IFN/RBV for 12 weeks. All of the study volunteers had HCV viral loads above 50,000; none of the patients had cirrhosis of the liver.

According to Kowdley's EASL report, 51 of the 52 patients completed 12 weeks of treatment; the remaining study volunteer was lost to follow-up during therapy. All 51 patients (100 percent) had an end-of-treatment response (ETR)—an undetectable HCV viral load after completing 12 weeks of therapy.

Data were available for 50 of the 51 study volunteers 12 weeks after completing therapy; one additional patient was lost to follow-up during this period.

Of the 50 evaluable patients, 47 of them—90 percent of the original 52 study group volunteers—still had an undetectable HCV viral load 12 weeks after completing treatment. Though HCV infection isn't considered cured until viral load testing confirms no measurable viral replication for 24 weeks following the completion of therapy (SVR 24), an SVR 12 is highly indicative of a favored outcome.

Three patients were dubbed relapsers—their HCV viral loads rebounded following the completion of 12 weeks of GS-7977 plus peg-IFN/RBV therapy.

Overall, Kowdley and his colleagues report, GS-7977 was well tolerated. The frequency and severity of side effects were consistent with those typically associated with peg-IFN/RBV therapy. The most common adverse events during the 12 weeks of therapy were fatigue, headache, nausea, chills and insomnia.

Other important GS-7977 data being presented at EASL include early SVR results from a study evaluating the nucleotide analog in combination with ribavirin—without pegylated interferon—in people with genotype 1 HCV. The results, indicating that 22 of 25 patients (88 percent) using this regimen for 12 weeks have undetectable viral loads four weeks after completing therapy, are to be presented at EASL on Saturday, April 21.

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