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From *TreatmentUpdate 227*

Germany—experience with Maviret after licensure

Maviret is the brand name of a pill containing two anti-HCV drugs—glecaprevir and pibrentasvir. Maviret has been approved in Canada, the U.S. and the European Union for the treatment of hepatitis C virus (HCV) infection. For further information about how Maviret is used, see the CATIE factsheet on this drug.

Clinical trials tend to enroll relatively healthy people, so it is important to test newly licensed drugs in the people who attend clinics to get a better idea of the effects of the drug in a wider population.

Researchers in Germany collaborated in a large study with adults who had chronic HCV infection who either had not previously received HCV treatment or whose past treatment with interferon or the combination of sofosbuvir and ribavirin had failed. Data were collected between July 2017 and February 2018. In total, 321 people have completed treatment in this analysis and viral load information is still being collected. However, researchers confirmed that 96 people have been cured and 225 are currently being monitored.

The average profile of participants was as follows:

- 68% male, 32% female
- age – 47 years
- HCV viral load – 1.5 million IU/mL
- 90% had not previously been treated
- 71% had another co-existing health condition (such as cardiovascular disease)

The distribution of genotypes was as follows:

- GT 1a – 34%
- GT 1b – 17%
- GT 2 – 7%
- GT 3 – 35%
- GT 4 – 5%
- GT 5 or 6 – less than 1%

Most (98%) participants were treated with an eight-week regimen and the remaining 2% with a 12-week regimen.

Results

Three participants left the study prematurely, in two cases because of diarrhea or nausea. One participant stopped visiting the clinic. None of these people had serious symptoms of liver injury.

Among the remaining 93 patients who were cured and whose data were complete, common adverse events reported in the study were as follows:

- lack of energy – 9%
- headache – 8%

Such symptoms are commonly seen in people who have been treated with direct-acting antivirals (DAAs), regardless of the DAAs used, and resolve after a course of treatment has finished.

Severely abnormal blood test results were rare and occurred in three people. In two cases this was because of elevated liver enzymes, and in the third it was due to elevated levels of the waste product bilirubin. These abnormal blood test results were temporary.

The results from this observational study in Germany are very similar to the results seen with Maviret in clinical trials.

—Sean R. Hosein

REFERENCE:

Berg T, Stoehr A, Pangerl A, et al. First real-world data on safety and effectiveness of glecaprevir/pibrentasvir for the treatment of patients with chronic hepatitis C virus infection: data from the German Hepatitis C registry. *International Liver Congress,* 11-15 April 2018, Paris, France. Presentation GS-007

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