New TMC435 Trials Open for Hep C Patients With Genotype 1 and 4

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The first study, HPC3001, is enrolling people living with genotype 1 hepatitis C virus (HCV) infection who were unsuccessfully cured with pegylated interferon and ribavirin. The second study, HPC3011, is open to people living with genotype 4 HCV infection who are either starting therapy for the first time or require retreatment.

In Phase II clinical trials, TMC435 was well tolerated and only required once-daily dosing. It has shown promise, when combined with pegylated interferon and ribavirin, for people with genotype 1 HCV starting therapy for the first time. And in the Phase IIb ASPIRE study, TMC435 plus pegylated interferon and ribavirin demonstrated strong efficacy potential for genotype 1 patients requiring retreatment, notably relapsers, partial responders and null responders to prior therapy.

HPC3001 is comparing TMC435 with Incivek (telaprevir), each in combination with pegylated interferon and ribavirin in people living with genotype 1 HCV who were null or partial responders to prior pegylated interferon and ribavirin treatment.

The study aims to enroll 744 volunteers and prove the efficacy of TMC435-based therapy, compared with approved Incivek-based treatment, in this historically difficult-to-treat population.

Study volunteers will receive TMC435 150 milligrams (mg) once daily or telaprevir 750 mg administered every eight hours in combination with pegylated interferon/ribavirin for 12 weeks followed by 36 weeks of pegylated interferon/ribavirin alone.

Unlike the randomized design of HPC3001, HPC3011 is a single-group study evaluating TMC435's safety and effectiveness in 100 people living with genotype 4 HCV infection. Everyone in the study will receive 150 mg TMC435 plus pegylated interferon/ribavirin for 12 weeks, followed by pegylated interferon/ribavirin alone.

The actual length of treatment in HPC3011 will depend on early virologic responses to therapy. Patients will be able to stop treatment after 24 weeks if predefined response-guided criteria are met. However, study volunteers with liver cirrhosis upon entering the study will receive 48 weeks of therapy, irrespective of on-treatment virologic response and treatment history.

"We are extremely pleased to expand the Phase III program with these two new trials as we continue development of TMC435 for broad patient populations," said Charlotte Edenius, executive vice president of research and development and Medivir. "The 744 patient HPC3001 study is

aimed at further confirming the positive findings of the ASPIRE Phase IIb trial in genotype-1 non-responder patient populations, and in the HPC3011 study, the genotype-4 activity of TMC435 is being investigated.”

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