Press release 2007-11-21

Initiation of a phase IIa clinical trial with investigational hepatitis C protease inhibitor TMC435350

Medivir (OME: MVIRB SS) announced today that, following the successful completion of a phase I study in both healthy volunteers and patients chronically infected with hepatitis C virus (HCV), the phase IIa study, TMC435350-C201, of the investigational hepatitis C (HCV) protease inhibitor TMC435350. The study will start shortly in Europe by Tibotec Pharmaceuticals Ltd., who are collaborating with Medivir on the development of TMC435350.

TMC435350-C201 is a phase IIa proof-of-concept, blinded, randomized, placebo-controlled trial to assess the effectiveness, safety, tolerability, and pharmacokinetics of four different dose regimens of TMC435350 (25 mg daily, 75mg daily, 200mg daily, 400mg daily). 96 treatment-naïve and 24 treatment-experienced patients with chronic genotype-1 HCV infection will be enrolled in the trial which will be conducted at more than 20 sites in Europe. Patients will receive either TMC435350 or placebo once daily (qd) for 28-days. Standard of Care (SoC) treatment, peginterferon alpha-2a (Pegasys®) and ribavirin (Copegus®), will be provided for 48 weeks or, optionally, for 24 weeks for those patients with an undetectable HCV viral load at Week 4 and who remain undetectable at Week 20. Patients will be followed-up for 24 weeks after the end of SoC to allow evaluation of sustained virologic response (SVR).

In the phase I study TMC435350 was administrated at 200 mg qd for five days to patients chronically infected with genotype-1 hepatitis C virus (HCV). The viral load reductions met the target set for the trial. These results will be submitted for presentation at the Annual Meeting of the European Association for the Study of the Liver in Milan in April 2008

The earlier phase I study results were reported at the AASLD Liver Meeting in Boston, November 2-6 2007. They showed that in this study TMC435350 was generally well-tolerated when given to HCV-negative healthy volunteers at single oral doses up to 600 mg, and at 5 days of oral doses up to 400 mg. The plasma levels of TMC435350 24 hours after day 5 dosing at 200 mg qd were more than 250-fold in excess of the HCV replicon EC50 value.

For more information about the phase IIa study, visit www.clinicaltrials.gov

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