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Phase IIa data on TMC435350 in patients with hepatitis C to be presented at AASLD

Medivir today announced that three abstracts related to TMC435350 have been accepted for poster presentations at the upcoming 59th Annual Meeting of the American Association for Study of Liver Diseases (AASLD) meeting in San Francisco October 31 - November 4. The abstracts for these presentations have been published today and are available on Hepatology web site (AASLD).

TMC435350 is an investigational protease inhibitor, being developed by Tibotec in partnership with Medivir, for the treatment of hepatitis C virus (HCV). Clinical results from the ongoing phase IIa trial (OPERA-1) will be presented in two posters and a third poster will present preclinical results.

1. Safety and antiviral activity of TMC435350 in treatment-naïve genotype 1 HCV-infected patients – M Manns et al.
2. Pharmacokinetics of TMC435350, with and without pegIFN and ribavirin, in HCV-infected individuals – G van't Klooster et al.
3. Inhibitory activity of TMC435350 on HCV NS3/4A proteases from genotype 1 to 6 – T Lin et al.

The phase IIa proof-of-concept trial (OPERA- 1) is a blinded, randomized and placebo-controlled trial to assess the antiviral activity, safety and pharmacokinetics of once-daily (QD) regimens of TMC435350 in HCV genotype 1 patients. Patients are treated with TMC435350 or placebo once-daily for 4 weeks (28-days) in addition to Standard of Care (SoC) treatment peginterferon alpha-2a (Pegasys®) and ribavirin (Copegus®), which is then continued for another 20 or 44 weeks. Results from Cohort 1, 25mg or 75mg TMC435350 versus placebo, will be reported at AASLD

"These data demonstrate the potent antiviral activity of TMC435350 against genotype-1 HCV", says Lars Adlersson, CEO & President at Medivir. "Based on these clinical and non-clinical studies, we are confident that TMC435350 has the potential to become a valuable addition to available therapy, providing an efficacious treatment with once-daily dosing". OPERA-1 is currently recruiting patients to evaluate higher doses in treatment-naïve HCV patients, as well as those who have not responded or have relapsed on previous SoC treatment.

Safety and antiviral activity of TMC435350 in treatment-naïve genotype 1 HCV-infected patients

50 patients were enrolled in Cohort 1 and treated with either TMC435350 or placebo for 7 days followed by TMC435350 or placebo with SoC for 3 weeks, or TMC435350 or placebo with SoC for 4 weeks. All patients thereafter continued on SoC. The rapid viral response, RVR, defined as HCV RNA less than 10 IU/mL was evaluated at 4 weeks.

TMC435350 at doses of 25mg and 75mg QD demonstrated dose-dependent antiviral activity, both alone and in combination with SoC.

In the 75mg 4-week triple therapy group, 9/9 patients achieved HCV RNA below lower limit of quantification (<25 IU/mL), of whom 8 (of 9) patients achieved undetectable HCV RNA (<10 IU/mL) at day 28 **(RVR=89%)**.

No serious or severe adverse events were related to TMC435350. There were no safety-related treatment discontinuations, and no dose related safety findings. Most common adverse events associated with TMC435350 were nausea, diarrhea and headache.

Pharmacokinetics of TMC435350, with and without pegIFN and ribavirin, in HCV-infected individuals
Pharmacokinetic properties of TMC435350 in healthy volunteers (200mg) and in HCV-infected individuals from two dose groups (25mg and 75mg) in the OPERA-1 trial are presented. For both dosing regimens in HCV infected patients, steady state was readily achieved after three days of once-daily dosing with plasma concentrations essentially proportional to the dose. The plasma trough levels were approximately 10 to 30-fold higher than projected effective levels (EC_{50} in replicon).

Inhibitory activity of TMC435350 on HCV NS3/4A proteases from genotype 1 to 6
TMC435350 is a potent inhibitor of NS3/4A proteins from genotypes 1 to 6, with IC_{50} values below 10nM for all HCV NS3/4a enzymes tested with the exception of genotype 3 protease at 100nM. The compound binds non-covalently with fast association and slow dissociation from the protease.

About hepatitis C
Chronic infection with the hepatitis C virus (HCV) leads to liver diseases. According to the WHO, 3% of the global population is infected with HCV, which means 200 million individuals. In the USA, 1.8% of the population is infected, that is 3.9 million people. In more than 60% of these cases, the HCV infection leads to chronic liver disease, cirrhosis and liver tumors. It is the most common reason for liver transplant. The HCV market is currently dominated by interferon-based treatments.

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For further information on Medivir, please see our website: www.medivir.se