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First data on TMC435350 in patients with hepatitis C who have failed previous treatment shows antiviral activity

The data from a small explorative study will be presented tomorrow at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL) in Milan, Italy. These are the first data to be presented on the use of TMC435350 in Hepatitis C patients. There will also be a poster presentation under the title; "Once-daily regimens of the HCV NS3/4A-protease inhibitor TMC435350 are predicted to provide therapeutic exposure in plasma and liver".

Medivir and Tibotec Pharmaceuticals Ltd discovered TMC435350 through a research collaboration. TMC435350 is a potent inhibitor of the hepatitis C virus (HCV) NS3/4A serine protease and is presently in a phase IIa proof-of-concept trial (OPERA- 1) in Europe.

Data about the study

The objective of the phase Ia study was to evaluate, pharmacokinetics and safety of TMC435350 in healthy volunteers and pharmacokinetics, safety and antiviral activity in HCV infected patients in the following 1b study. The study included 52 healthy volunteers and 6 patients with HCV infection who were given TMC435350.

Results from the phase Ib study

Five days dosing with 200 mg TMC435350 dosed once-daily resulted in a median reduction of viral load of 3.9 $\log_{10}$ units/mL on day 6. Rapid decline in HCV viral load was observed in all patients, both genotype 1a and 1b. There was no viral breakthrough observed during dosing or in the following three days. At a four week follow-up, plasma levels of HCV-RNA had returned to baseline in all patients. Observed adverse events in patients and healthy volunteers were all assessed as being mild and no serious adverse events were observed. There were no study-medication related discontinuations.

Conclusion

TMC435350 was well tolerated during five days of dosing and exhibited strong and rapid antiviral activity in HCV genotype 1 infected patients. The results of this phase I trial in both healthy volunteers and patients with HCV infection formed the basis for the ongoing phase IIa trial throughout Europe.

The poster to be presented at EASL could be found at www.medivir.com /Investor & Media/Latest events

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