

Clinical Update – Debio 025 in Hepatitis C

Debiopharm presents promising phase IIa results showing potent antiviral activity

Lausanne, Switzerland, April 28, 2009 - Debiopharm Group (Debiopharm), a global biopharmaceutical development specialist that focuses on serious medical conditions, particularly in the field of oncology, presented results from a phase IIa study with Debio 025, a selective cyclophilin (Cyp) inhibitor with a potent anti-hepatitis C (HCV) effect. Revealed at the 44th Annual Meeting of the European Association for the Study of the Liver, in Copenhagen, these findings showed potent antiviral activity.

The phase IIa study investigated the efficacy and safety of Debio 025 in combination with Peg interferon alpha 2a (peg-IFN α 2a) and ribavirin in previously null-responder genotype 1 HCV patients. Results demonstrated that Debio 025 at doses of 400 mg (with initial loading) and 800 mg daily for 29 days shows a statistically significant reduction of HCV RNA of respectively -1.96 log (-98.9%) and -2.38 log (-99.5%) when co-administered with Peg-IFN alpha-2a and ribavirin in previous null responders.

“These results in patients who are highly unlikely to respond to re-treatment with an interferon-based regimen, are very important to us, as they confirm that Debio 025 is a potent anti-HCV agent,” said Rolland-Yves Mauvernay, President and Founder of Debiopharm Group. “We are making it our mission to find a cure for this widely spread and life threatening disease and these findings bring us one step closer to our goal.”

About the phase IIa triple therapy study

Debiopharm investigated different dosing regimens of Debio 025 in combination with peg-IFN α 2a at 180 micrograms/week and ribavirin at 1000/1200 mg/day in genotype 1 chronic HCV patients that were previously null responders ($< 2 \log_{10}$ HCV-RNA reduction after 12 weeks with peg-IFN α 2a and ribavirin). Fifty patients were randomised in an open phase IIa study to receive one of five treatment regimens for 29 days. Afterwards patients continued treatment on Peg-IFN alpha-2a and Ribavirin. A loading dose of Debio 025 at the start of treatment accelerates the onset of action and enhances efficacy in the early stage of treatment.

About Debio 025

Debio 025 is a synthetic first-in-class Cyp inhibitor, being tested in humans as a potential anti-HCV drug. Debio 025 binds strongly to Cyp, host cell proteins thought to confer a replication advantage to HCV. Its potent inhibitory activity on the HCV replication was shown in the following clinical studies. Results of a phase Ib study demonstrate that Debio 025 monotherapy for 15 days induced a strong anti-HCV effect (3.6 \log_{10} reduction) in HIV-1/HCV co-infected patients. (*Hepatology*, 47:817-26). Results of a phase IIa study with Debio 025 indicate that Debio 025 shows an important additive anti-HCV effect (4.6 \log_{10} reduction) when co-administered with peg-IFN α 2a to treatment-naïve HCV patients. (*Hepatology*, in press)

About HCV

Globally, an estimated 170 million persons are chronically infected with HCV and 3 to 4 million are newly infected each year. HCV, in combination with hepatitis B, now accounts for 75% of all cases of liver disease around the world. HCV is considered by the World Health Organization as an epidemic. Because HCV can infect a patient for decades before being discovered, it is often called the "silent" epidemic. Studies suggest that in the US alone, nearly 4 million people are or have been infected with HCV and of these, 2.7 million have an ongoing chronic infection, the majority being between 40 to 60 years old.

About Debiopharm Group

Debiopharm Group is a global biopharmaceutical development specialist that in-licenses promising biological and small molecule drug candidates. It develops its products for global registration and maximum commercial potential. Once registered, the products are out-licensed to pharmaceutical partners for sales and marketing.

Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

Founded in 1979 and headquartered in Lausanne, Switzerland, Debiopharm has developed three products with global combined sales in excess of \$2.6 billion in 2008.

For more information on Debiopharm Group, please visit: www.debiopharm.com.

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