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Clinical Update – Debio 025 in Hepatitis C

Debiopharm starts phase IIb study after record time patient randomisation

Lausanne, Switzerland, April 30, 2009 - Debiopharm Group (Debiopharm), a global biopharmaceutical development specialist that focuses on serious medical conditions, particularly in the field of oncology, announced that on April 7, 2009 the last patient was randomised to take part in a phase IIb clinical study with Debio 025, a selective cyclophilin (Cyp) inhibitor with a potent anti-hepatitis C (HCV) effect. In a record time of three months, a total of 290 patients were randomised in seven countries, including Poland, Germany, Belgium, France, Spain, Italy and Romania. This double-blind, placebo-controlled, parallel-group study will investigate the efficacy and safety of three different treatment regimens combining Debio 025 with Peg interferon alpha 2a (peg-IFN α 2a) and ribavirin in treatment naïve chronic HCV genotype 1 patients.

"We are proud to have randomised our patients in such a short period, this demonstrates the investigator's confidence in our product," said Rolland-Yves Mauvernay, President and Founder of Debiopharm Group. "The efficiency of the recruitment is very motivating for us in our development of Debio 025, as we are eager to provide HCV patients with a more effective 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 log₁₀ 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 log₁₀ reduction) when co-administered with peg-IFNa2a 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 outlicensed 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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