

**CLINICAL UPDATE – DEBIO 025 CYCLOPHILIN INHIBITOR  
FOR THE TREATMENT OF HCV  
- A unique viral kinetics profile -**

**LAUSANNE, Switzerland, April 19, 2007** – Debiopharm Group (Debiopharm), a global independent biopharmaceutical development specialist in oncology and serious medical conditions, presented additional results of a previous phase Ib, 15 day study with cyclophilin (Cyp) inhibitor Debio 025 in HIV/HCV (hepatitis C virus) co-infected patients. The data were presented at the 42<sup>nd</sup> Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona, Spain. Mathematical modelling of the viral decay shows that Debio 025 has a unique viral kinetics profile without signs of emerging resistance during short term treatment.

Other data from the same study showed that during treatment, Cyp-B levels decreased significantly in peripheral blood mononuclear cells (PBMCs) after treatment with Debio 025. The drop in Cyp-B levels paralleled the 3.6 log<sub>10</sub> decrease reported earlier in this study. These human data confirm previous *in vitro* results that have shown that Cyp-B inhibition leads to the depletion of intracellular Cyp-B levels in the HCV replicon, as well as in other cell culture models. These are the first preliminary human data that support the hypothesis that intracellular CypB depletion is associated with significant anti-HCV activity and that CypB inhibition is a valid new target for the development of anti-HCV drugs.

“We are very excited about these results. To date, we have finalised the first two cohorts of our phase IIa study in treatment-naïve mono-infected HCV patients, where we examined the effect of increasing doses of Debio 025 in combination with pegylated interferon. The Data Management Committee has analysed all safety and efficacy data and authorised the initiation of the cohort with the highest dose in the protocol,” said Kamel Besseghir, CEO of Debiopharm S.A.

**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 cyclophilins, host cell proteins thought to confer a replication advantage to HCV. Its potent inhibitory activity on the HCV replication was shown in preclinical studies.

Previous results of the phase Ib study demonstrate that Debio 025 monotherapy for 15 days induced a strong anti-HCV effect (3.6 log<sub>10</sub> reduction) in HIV-1/HCV coinfecting patients. CypA and CypB levels were measured in patients' PBMCs to investigate the relationship between CypA/CypB inhibition and antiviral effect. (*October 31, 2006 press release*).

## **About HCV**

HCV is the most prevalent liver disease in the world and 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 over 200 million people worldwide are infected with HCV, an overall incidence of around 3.3% of the world's population. 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. A fourfold increase in the number of adults diagnosed with chronic HCV infection is projected from 1990 to 2015, since most persons with chronic HCV infection have yet to be diagnosed but are likely to come to medical attention in the next decade.

## **About Debiopharm Group**

Debiopharm Group is a global biopharmaceutical development specialist that in-licenses promising biologics and small molecule drug candidates. Debiopharm develops its products for global registration and maximum commercial potential for out-licensing 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 2006.

For more information on Debiopharm Group, please visit: [www.debiopharm.com](http://www.debiopharm.com).

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