

Novartis Gains Exclusive Rights To Debio 025, An Antiviral Agent In Phase IIb Development As Potential First-in-class Hepatitis C Therapy

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Novartis has gained exclusive rights to develop and market Debio 025 (alisporivir), a potential first-in-class antiviral agent currently in Phase IIb development for the treatment of hepatitis C. Debio 025 is the first in a new class of drugs called cyclophilin inhibitors which could become part of the future standard of care for the disease.

Debio 025 has been in-licensed from Debiopharm Group(TM), an independent biopharmaceuticals company based in Switzerland, under an agreement which gives Novartis exclusive worldwide development and marketing rights (excluding Japan). Under the terms of the agreement, Novartis will make an upfront payment to Debiopharm, and Debiopharm will be eligible for milestone payments, and for royalties on future sales of Debio 025, if it is approved. The transaction is subject to customary regulatory approvals.

"Hepatitis C is sometimes referred to as a 'silent epidemic' because the virus can lie dormant in the body for years or even decades before the symptoms become apparent," said David Epstein, CEO of the Novartis Pharmaceuticals Division. "Novartis is dedicated to developing medicines that will reduce the impact of this disease on patients, and we believe that Debio 025 could prove an important step forward by significantly enhancing the efficacy of existing therapy that forms the standard of care for hepatitis C."

More than 170 million people worldwide are infected with hepatitis C virus (HCV)³, and this can cause serious liver disease leading to cirrhosis or liver cancer which may result in death. There is an urgent need for more effective medications, often used in combination, as current therapy is only effective in around 50% of patients with the most prevalent form of the virus, called genotype 1².

Cyclophilin inhibitors such as Debio 025 provide a novel approach to treatment by targeting host proteins that are involved in the growth of the hepatitis C virus. Results of a Phase II study show that Debio 025 significantly reduced HCV replication when used alone, and had an important additive anti-HCV effect (4.6 log₁₀ reduction) in combination with pegylated interferon alfa-2a in treatment-naïve patients¹. No significant safety issues have been identified so far.

A double-blind, placebo-controlled Phase IIb study is now under way to assess the efficacy and safety of Debio 025 in combination with the current standard of care for hepatitis C - peginterferon alfa-2a plus ribavirin - in treatment-naïve patients. The study is being conducted in patients with the most common genotype 1. Debio 025 is also effective against other genotypes of the virus^{1,4}.

The in-licensing of Debio 025 represents a further expansion of the Novartis hepatitis C portfolio following the filing of Joulferon®/Zalbin® (albinterferon alfa-2b) for European and US regulatory approval at the end of 2009. In Phase III studies, Joulferon dosed every two weeks showed similar efficacy to peginterferon alfa-2a dosed weekly while requiring half the number of injections. Albinterferon alfa-2b is being developed and will be co-commercialized in the US together with Human Genome Sciences, who filed for US approval under the brand name Zalbin®.

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References

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