



## INCIVO® (Telaprevir) Demonstrates Efficacy and Increased Cure Rates among Cirrhotic Patients with Genotype-1 Chronic HCV Compared to Standard of Care

### Data presented at AASLD 2011 highlights efficacy in typically hard to treat patients

**San Francisco, United States, 5th November 2011** - Janssen Pharmaceutica NV (Janssen), today presented new data for INCIVO® (telaprevir) at the American Association for the Society of Liver Disease (AASLD) Annual Meeting, highlighting the safety and efficacy of a telaprevir based regimen in cirrhotic patients who had previously failed treatment. Results from a sub-analysis of the REALIZE Phase 3 study showed that telaprevir, in combination with peginterferon alfa and ribavirin (PR), was associated with cure rates (defined as a sustained virologic response (SVR)) significantly higher than PR alone in patients with genotype-1 chronic HCV and cirrhosis (47 percent vs 10 percent respectively).<sup>1</sup> HCV is a curable condition in the majority of cases, however, if left untreated can result in serious long-term health problems including cirrhosis. Cirrhosis causes permanent scarring of the liver which can eventually lead to liver failure and mortality.

Results showed that cirrhotic patients experienced significantly higher cure rates following treatment with a telaprevir-based regimen compared with PR alone. Overall, cirrhotic patients had lower cure rates than those without cirrhosis (except previous treatment relapsers), however, treatment with a telaprevir-based regimen cured nearly half of all patients with cirrhosis.<sup>1</sup>

"This year has seen significant advances in the treatment of HCV with the availability of direct-acting antivirals (DAAs), including telaprevir. This is even more important for those patients who are experiencing the potentially devastating effects of HCV, such as cirrhosis. The REALIZE sub-analysis demonstrates that telaprevir maintains superior efficacy compared to PR alone in a group of patients that is typically hard to treat." said Prof. Stanislas Pol, Lead Study Investigator, Université Paris Descartes, Inserm U-1016 and Liver Department, H<sup>T</sup>pital Cochin, Paris, France.

REALIZE was a randomised, double-blind, placebo-controlled Phase 3 trial to compare the efficacy, safety and tolerability of telaprevir in 662 patients with chronic genotype-1 HCV who failed prior treatment with PR. Patients received 48 weeks total treatment with PR alone or one of two telaprevir-based regimens (T/PR): 12 weeks T/PR plus 36 weeks PR alone, or 4 weeks PR alone followed by 12 weeks T/PR and 32 weeks PR alone.<sup>2</sup> In this sub-analysis, efficacy and safety variables were reanalysed for 662 patients with and without baseline cirrhosis.<sup>1</sup>

Adverse events were consistent with those reported in the Phase 3 studies. Rash, pruritus and anemia (Hb <10 g/dL) were more frequent in cirrhotic patients receiving telaprevir (42%, 53% and 39% respectively) than PR alone. Adverse events led to discontinuation of telaprevir in 15% of cirrhotic and 12% of non-cirrhotic patients.<sup>1</sup>

Telaprevir was approved by the European Commission for the treatment of genotype-1 chronic HCV in previously untreated and treatment-experienced patients in combination with peginterferon alfa and ribavirin in September 2011. The approval was based on the results of three Phase 3 studies in 2,290 patients: ADVANCE, ILLUMINATE and REALIZE.<sup>3,4,2</sup>

### Additional telaprevir data being presented at AASLD include:

- Further analysis of the REALIZE study confirms that prior response to treatment may be a more accurate predictor of achieving a cure with telaprevir than response to a 4 week lead in. Prior relapsers or partial responders who had a poor response after 4-week lead-in phase with PR achieved substantially higher cure rates in response to the telaprevir based regimen than prior null responders, despite similar responses at this time point.<sup>5</sup> This study highlights the value of prior response categorisation to predict response to telaprevir.
- An interim analysis of the EXTEND study highlighted that 99% of patients who achieved a cure after receiving telaprevir maintained undetectable HCV RNA at a median follow-up of 21 months.<sup>6</sup> One patient had a late relapse 44 weeks after early study dosing discontinuation. Among patients not achieving a cure, variants associated with telaprevir resistance were no longer observed in 83% of patients at a median follow up of 29 months.<sup>6</sup>

### About INCIVO®

INCIVO® will be made available by the Janssen Pharmaceutical Companies of Johnson and Johnson in certain countries in the European Union. Telaprevir was developed by Tibotec Virco-Virology BVBA, one of the Janssen Pharmaceutical Companies, in collaboration with Vertex and Mitsubishi Tanabe Pharma. The Janssen Companies have the right to commercialise telaprevir in Europe, Latin America, the Middle East, Africa, India, Australia and New Zealand under the commercial name INCIVO®; Vertex has the right to commercialize telaprevir in North America under the name INCIVEK™ (approved by US FDA in May 2011 and

Health Canada in August 2011 for genotype-1 chronic hepatitis C with compensated liver disease); Mitsubishi Tanabe Pharma has the right to commercialise telaprevir in Japan and certain Far Eastern countries.

### **Important Safety Information**

Please see full Summary of Product Characteristics or visit <http://www.emea.europa.eu> for more details.

### **About HCV**

HCV is a blood-borne infectious disease that affects the liver.<sup>7,8</sup> With an estimated 170 million people infected worldwide, and three to four million people newly infected each year, HCV puts a significant burden on patients and society.<sup>9</sup> Estimations indicate that HCV caused more than 86,000 deaths and 1.2 million disability-adjusted life-years (DALYs) in the WHO European region in 2002.<sup>10</sup> Most of the DALYs (95%) were accumulated by patients in preventable disease stages.<sup>10</sup> Chronic infection with HCV can lead to liver cancer and other serious and fatal liver diseases. About one-quarter of the liver transplants performed in 25 European countries in 2004 were attributable to HCV.<sup>10</sup> The previously accepted standard treatment for HCV is peginterferon alfa combined with ribavirin,<sup>11</sup> however this only cures 40-50 percent of genotype-1 chronic HCV patients.<sup>12</sup>

### **About Janssen**

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases.

Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

More information can be found at [www.janssen-emea.com](http://www.janssen-emea.com).

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. The Janssen Pharmaceutical Companies and Johnson & Johnson do not undertake to update any forward-looking statements as a result of new information or future events or developments.*

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