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INCIVO® (TELAPREVIR) DATA TO BE PRESENTED AT AASLD AND ISPOR, TWO MAJOR INTERNATIONAL CONGRESSES, ON THE ANTI-VIRAL RESPONSE, SAFETY, TOLERABILITY AND COST-EFFECTIVENESS OF AN INCIVO® (TELAPREVIR) BASED REGIMEN IN THE TREATMENT OF GENOTYPE-1 CHRONIC HEPATITIS C

Beerse, Belgium, 1 November, 2013 - Janssen Infectious Diseases-Diagnostics BVBA (Janssen) will present new data for INCIVO® (telaprevir) in combination with peginterferon alfa and ribavirin (PR) at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington D.C., highlighting that earlier treatment improves patient outcomes. In addition, Janssen will present data at the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) 16th European Congress in Dublin, Ireland, highlighting significant economic benefits associated with the use of a telaprevir-based regimen in a French patient population.

To date more than 110,000 patients have been treated with a telaprevir-based regimen globally[1] and triple therapy including a protease inhibitor remains the standard of care for patients with genotype-1 chronic HCV. Janssen continues to undertake clinical studies with telaprevir to identify opportunities to serve specialized and hard-to-treat patients in need of new therapeutic options for HCV.

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Earlier treatment improves outcomes

A retrospective analysis of 1642 patients who participated in the pivotal telaprevir phase 3 studies explored treatment response by disease stage. It found that the safety and efficacy of telaprevir varied by fibrosis stage, with F0–F1 and F2 patients (mild to moderate liver disease) demonstrating a similar outcome, and these patients were more likely to achieve a sustained viral response than patients with more advanced disease. The gain in efficacy of telaprevir for F2 over F3/F4 was unaccompanied by excess risk of adverse events.[2]

Cost-effectiveness data in French patient population

A Markov model analysis to be presented at ISPOR observes that treating F2 patients with telaprevir is expected to result in better clinical outcomes, and even though it may yield a higher cost compared to delaying treatment, it should be considered as an efficient choice by the French healthcare system based on its estimated incremental cost-effectiveness ratio of €37,197/QALY gained.[3] A further study showed that delaying treatment until new regimens become available is not the most efficient option for the French Healthcare system as the likely total costs incurred would be higher for the new regimen versus a triple therapy regimen with telaprevir, and may present a challenge to payers (ISPOR abstract ID: 44612).[4]

“Cost is a key factor in decision-making by healthcare providers across the globe and it is encouraging that we are able to show that early treatment with a telaprevir-based regimen can provide potential cost benefits to health authorities,” said Gaston Picchio, Hepatitis Disease Area Leader, Janssen. “With our continued efforts of studying the efficacy and safety of telaprevir, Janssen is demonstrating its commitment to addressing the unmet needs of patients in these HCV patient groups.”

Additional INCIVO® (telaprevir) data to be presented this week include:

- Pre-treatment IP-10 levels and IL28B genotype as predictive markers for SVR in treatment-naïve patients with genotype 1 HCV infection treated with telaprevir/peginterferon/ribavirin in the OPTIMIZE study.[5] (Abstract ID: 1852; Session Title: HCV Therapeutics: Approved Agents; 5 November, 2013; 8:00)

- Predictive factors of premature discontinuation of triple therapy in the international telaprevir early access program.[6] (Abstract ID: 1875; Session Title: HCV Therapeutics: Approved Agents; 5 November, 2013; 8:00)
- Real-life data of telaprevir-based triple-therapy in patients with chronic hepatitis C GT1 in Germany - A 48 week interim analysis.[7] (Abstract ID: 1900; Session Title: HCV Therapeutics: Approved Agents; 5 November, 2013; 8:00)
- Cost-effectiveness analysis of telaprevir triple therapy for treatment-naive patients with chronic hepatitis C on the combined efficacy data of the ADVANCE and OPTIMIZE studies.[8] (Abstract ID: 1915; Session Title: HCV Therapeutics: Approved Agents; 5 November, 2013; 8:00)
- Telaprevir combination therapy in treatment-naïve and experienced patients co-infected with HCV and HIV.[9] (Abstract ID: 38; Session Title: Parallel 5: HCV Therapeutics: Real World Experience; 3 November, 2013; 15:15)
- Efficacy and safety results of treatment of patients over 65 years old with genotype 1 Hepatitis C with severe fibrosis or compensated cirrhosis: the international telaprevir Early Access Program.[10] (Abstract ID: 1911; Session Title: HCV Therapeutics: Approved Agents; 5 November, 2013; 8:00)
- Treatment of Hepatitis C genotype 1 patients with severe fibrosis or compensated cirrhosis: efficacy results to week 16 on 1587 patients from the international telaprevir Early Access Program.[11] (Abstract ID: 1873; Session Title: HCV Therapeutics: Approved Agents; 5 November, 2013; 8:00)
- Management and outcomes of anemia in 1587 patients with Hepatitis C genotype 1 infection from the international telaprevir Early Access Program.[12] (Abstract ID: 1516; Session Title: HCV: Virology; 4 November, 2013; 8:00)

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About INCIVO® (telaprevir)

INCIVO® (telaprevir), in combination with peginterferon alfa and ribavirin (PR), is indicated for the treatment of genotype-1 chronic HCV in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve, and who have previously been treated with interferon alfa

(pegylated or non pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.[13] INCIVO® is a small molecule, selective inhibitor of the HCV serine protease, and a member of the new class of medicine for the treatment of genotype-1 chronic HCV, direct-acting antivirals (DAAs). Unlike previous treatments, DAAs act directly on viral enzymes and prevent the virus from replicating. INCIVO® was approved by the European Commission on the 19th September 2011.

INCIVO®, 1,125 mg (three 375 mg film-coated tablets) should be taken orally twice daily (BID) with food. Alternatively, 750 mg (two 375 mg tablets) can be taken orally every 8 hours (q8h) with food. The total daily dose is 6 tablets (2,250 mg).[13]

INCIVO® was developed by Janssen Infectious Diseases-Diagnostics BVBA, one of the Janssen Pharmaceutical Companies, in collaboration with Vertex Pharmaceuticals Incorporated (Vertex) and Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe Pharma). Janssen has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and certain other countries. Vertex has rights to commercialize telaprevir in North America where it is being marketed under the brand name INCIVEK™. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries where it is being marketed as TELAVIC®.

Important Safety Information

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

The overall safety profile of telaprevir is based on the Phase II/III clinical development programme containing 3,441 patients who received a telaprevir based regimen. In clinical trials, the incidence of adverse events of at least moderate intensity was higher in the telaprevir group than in the placebo group (both groups receiving peginterferon alfa and ribavirin). The most frequently reported adverse reactions (incidence ≥ 5.0%) of at least grade 2 in severity were anemia, rash, pruritus, nausea, and diarrhoea during the telaprevir treatment phase, and the most frequently reported adverse reactions (incidence ≥ 1.0%) of at least Grade 3 were anemia, rash, thrombocytopenia, lymphopenia, pruritus, and nausea. INCIVO® prescribing information includes special warnings and pre-cautions for use with regards

to rash including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and Stevens - Johnson syndrome (SJS)/Toxic Epidermal Necrolysis (TEN).[13]

Rash events were reported in 55% of patients with a telaprevir-based regimen compared to 33% of patients treated with peginterferon alfa and ribavirin only and more than 90% of rashes were of mild or moderate severity. Severe rashes were reported with telaprevir combination treatment in 4.8% of patients. Rash led to discontinuation of telaprevir alone in 5.8% of patients and 2.6% of patients discontinued telaprevir combination treatment for rash events compared to none of those receiving peginterferon alfa and ribavirin.[13]

Hemoglobin values of < 10 g/dl were observed in 34% of patients who received telaprevir combination treatment and in 14% of patients who received peginterferon alfa and ribavirin. In placebo-controlled Phase 2 and 3 trials, 1.9% of patients discontinued telaprevir alone due to anemia, and 0.9% of patients discontinued telaprevir combination treatment due to anemia compared to 0.5% receiving peginterferon alfa and ribavirin. [13]

About HCV

Hepatitis C (HCV) is a contagious liver disease which is spread through blood-to-blood contact and is usually symptomless at the outset.[14] With an estimated 150 million people infected worldwide, and three to four million people newly infected each year,[15] HCV puts a significant burden on patients and society.[16] Estimations indicate that HCV kills more than 499,000 people worldwide per year,[17] accounting for approximately 1% of deaths worldwide. It is the world's primary cause of cirrhosis and liver cancer[18] with an estimated 20-30% of patients developing liver cirrhosis[19] and a further 7% developing liver cancer.[20] Please visit www.stop-hepatitis-c.info for more information.

About Janssen

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in infectious diseases and vaccines, oncology, immunology, neuroscience, 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. Please visit www.janssen.com for more information.

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