May 7, 2014

Janssen Submits Supplemental New Drug Application to U.S. FDA for OLYSIO™ (Simeprevir) for Once-Daily Use in Combination with Sofosbuvir for 12 Weeks for the Treatment of Adult Patients with Genotype 1 Chronic Hepatitis C

Filing Includes Data from Treatment-Naïve Patients with Advanced Fibrosis and Null Responders with All Stages of Liver Fibrosis

RARITAN, New Jersey - May 7, 2014 - Janssen Research & Development, LLC (Janssen) today announced it has submitted a Supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for simeprevir, an NS3/4A protease inhibitor marketed as OLYSIO™ in the United States, in combination with the nucleotide analog NS5B polymerase inhibitor sofosbuvir developed by Gilead Sciences, Inc. This regulatory submission is for the treatment of genotype 1 chronic hepatitis C (HCV) in adult treatment-naïve patients with advanced fibrosis and null responders with all stages of liver fibrosis.

OLYSIO™ is currently approved for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. OLYSIO™ efficacy has been established in combination with peginterferon alfa and ribavirin in HCV genotype 1-infected patients with compensated liver disease, including cirrhosis.

"Hepatitis C places a significant burden on the lives of those infected and if left untreated may cause significant damage to the liver, including cirrhosis and complications such as liver failure," said Gaston Picchio, Hepatitis Disease Area Leader, Janssen Research & Development. "This filing brings us closer to potentially offering these patients a once-daily all-oral treatment combination that includes the direct-acting antiviral agents simeprevir and sofosbuvir."

The regulatory submission for OLYSIO™ and sofosbuvir is supported by data from the Phase 2 COSMOS study which include treatment-naïve patients with advanced fibrosis (METAVIR F3 to F4 scores) and null-responder patients with all stages of liver fibrosis (METAVIR F0 to F4 scores).

In April 2014, Janssen announced initiation of the Phase 3 OPTIMIST trials examining the safety and efficacy of simeprevir and sofosbuvir without interferon or ribavirin for the treatment of chronic genotype 1 HCV infection. In the first trial, known as OPTIMIST-1, the combination will be administered once daily for 8 or 12 weeks in chronic HCV genotype 1 infected patients without cirrhosis who are HCV treatment naive or treatment experienced. In the second trial, known as OPTIMIST-2, the combination will be administered once daily for 12 weeks in HCV genotype 1 infected patients with cirrhosis who are HCV treatment naive or treatment experienced. For more information please visit http://www.clinicaltrials.gov.

About Hepatitis C
Hepatitis C is a blood-borne infectious disease of the liver that affects approximately 3.2 million people in the United States and is a leading cause of chronic liver disease. Approximately 150 million people are infected with hepatitis C worldwide and 350,000 people per year die from the disease globally. When left untreated, hepatitis C can cause significant damage to the liver, including cirrhosis. Additionally, hepatitis C may increase the risk of developing complications from cirrhosis, which may include liver failure.

About OLYSIO™ (simeprevir)
OLYSIO™ is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment of chronic hepatitis C infection in combination with pegylated interferon and ribavirin in HCV genotype 1 infected patients with compensated liver disease, including cirrhosis.

Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB retains marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved for the treatment of chronic hepatitis C infection as part of an antiviral treatment regimen in combination with pegylated interferon and ribavirin in genotype 1 infected adults with compensated liver disease, including cirrhosis in September 2013 in Japan, in November 2013 in Canada and the U.S., and in March 2014 in Russia. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013 by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C and the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending Marketing Authorisation in the European Union for the use of simeprevir in combination with other medicinal products for the treatment of chronic HCV. This application is under review by the EMA.

Important Safety Information

What Is OLYSIO™?

- OLYSIO™ (simeprevir) is a prescription medicine used with other antiviral medicines, peginterferon alfa and ribavirin, to treat genotype 1 chronic (lasting a long time) hepatitis C in adults with stable liver problems.

- OLYSIO™ must not be taken alone. The efficacy of OLYSIO™ in combination with peginterferon and ribavirin is greatly decreased in patients who have genotype 1a Q80K. Please talk to your doctor about testing for genotype 1a Q80K and using a different therapy when genotype 1a Q80K is present.

- It is not known if OLYSIO™ is safe and effective in children under 18 years of age.

What is the most important information I should know and who should not take OLYSIO™ (simeprevir)?

- OLYSIO™, in combination with peginterferon alfa and ribavirin may cause birth defects or death of your unborn baby. If you are pregnant or your sexual partner is pregnant, or plans to become pregnant, do not take these medicines. You or your sexual partner should not become pregnant while taking OLYSIO™ with peginterferon alfa and ribavirin and for 6 months after treatment is over.
    - **Females and males must use two effective forms of birth control during treatment and for 6 months after treatment with OLYSIO™, peginterferon alfa, and ribavirin combination therapy.** Talk to your healthcare provider about forms of birth control that may be used during this time.

    - Females must have a pregnancy test before starting treatment with OLYSIO™, peginterferon alfa, and ribavirin combination therapy, every month while being treated, and every month for 6 months after your treatment with OLYSIO™, peginterferon alfa, and ribavirin combination therapy is over.

    - If you or your female sexual partner becomes pregnant while taking OLYSIO™, peginterferon alfa, and ribavirin combination therapy or within 6 months after you stop taking these medicines, tell your healthcare provider right away. You or your healthcare provider should contact the Ribavirin Pregnancy Registry by calling 1-800-593-2214. The Ribavirin Pregnancy Registry collects information about what happens to mothers and their babies if the mother takes ribavirin while she is pregnant.

- OLYSIO™ in combination with peginterferon alfa and ribavirin may cause rashes and skin reactions to sunlight. These rashes and skin reactions to sunlight can be severe and you may need to be treated in a hospital. Rashes and skin reactions to sunlight are most common during the first 4 weeks of treatment, but can happen at any time during treatment with OLYSIO™, peginterferon alfa, and ribavirin combination therapy.
    - Use sunscreen, and wear a hat, sunglasses, and protective clothing when you will be exposed to sunlight during treatment with OLYSIO™.
    - Limit sunlight exposure during treatment with OLYSIO™.
    - Avoid use of tanning beds, sunlamps, or other types of light therapy during treatment with OLYSIO™.
    - Call your healthcare provider right away if you get any of the following symptoms:
        - burning, redness, swelling or blisters on your skin
        - mouth sores or ulcers
        - red or inflamed eyes, like "pink eye" (conjunctivitis)

- Do not take OLYSIO™ alone. OLYSIO™ should be used together with peginterferon alfa and ribavirin to treat chronic hepatitis C infection.

What should I tell my healthcare provider before taking OLYSIO™?

- **Before taking OLYSIO™, tell your healthcare provider if you:**
    - have liver problems other than hepatitis C virus infection
    - have taken the medicines telaprevir (Incivek®) or boceprevir (Victrelis®)
    - had a liver transplant
    - are receiving phototherapy
    - have any other medical condition
    - are of East Asian descent
    - are breastfeeding. It is not known if OLYSIO™ passes into your breast milk. You and your healthcare provider should decide if you will take OLYSIO™ or breastfeed. You should not do both.
- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- OLYSIO™ and other medicines may affect each other. This can cause you to have too much or not enough OLYSIO™ or other medicines in your body, which may affect the way OLYSIO™ or your other medicines work, or may cause side effects. Do not start taking a new medicine without telling your healthcare provider or pharmacist.

- **Especially tell your healthcare provider if you take any of the following medicines:** amiodarone (Cordarone®, Pacerone®), amlodipine (Norvasc®), atazanavir (Reyataz®), atorvastatin (Lipitor®, Caduet®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®), cisapride (Propulsid®, Propulsid Quicksolv®), clarithromycin (Biaxin®, Prevpac®), cobicistat-containing medicine: (Stribild®), cyclosporine (Gengraf®, Neoral®, Sandimmune®), darunavir (Prezista®), delavirdine mesylate (Rescriptor®), dexamethasone (when administered by injection or when taken by mouth), digoxin (Lanoxin®), diltiazem (Cardizem®, Dilacor XR®, Tiazac®), disopyramide (Norpace®), efavirenz (Sustiva®, Atripla®), erythromycin (E.E.S.®, Eryc®, Ery-Tab®, Erythrocin®, Erythrocin Stearate®), etravirine (Intelence®), felodipine (Plendil®), flecainide (Tambocor®), fluconazole (when taken by mouth or when administered by injection) (Diflucan®), fosamprenavir (Lexiva®), indinavir (Crixivan®), itraconazole (when taken by mouth) (Sporanox®, Onmel®), ketoconazole (when taken by mouth) (Nizoral®), lopinavir (Kaletra®), lovastatin (Advicor®, Altoprev®, Mevacor®), mexiletine (Mexitil®), midazolam (when taken by mouth), milk thistle (Silybum marianum) or products containing milk thistle, nelfinavir (Viracept®), nevirapine (Viramune®, Viramune XR®), nicardipine (Cardene®), nifedipine (Adalat CC®, Afeditab CR®, Procardia®), nisoldipine (Sular®), oxcarbazepine (Trileptal®), phenobarbital (Luminal®), phenytoin (Dilantin®, Phenytek®), pitavastatin (Livalo®), posaconazole (when taken by mouth) (Noxafil®), pravastatin (Pravachol®), propafenone (Rythmol SR®), quinidine (Nuedexta®, Duraquin®, Quinaglute®), rifabutin (Mycobutin®), rifampin (Rifadin®, Rifamate®, Rifater®), rifapentine (Priftin®), ritonavir (Norvir®), rosuvastatin (Crestor®), saquinavir mesylate (Invirase®), sildenafil (Revatio®, Viagra®), simvastatin (Zocor®, Vytorin®, Simcor®), sirolimus (Rapamune®), St. John's wort (Hypericum perforatum) or products containing St. John's wort, tacrolimus (Prograf®), tadalafil (Adcirca®, Cialis®), telithromycin (Ketek®), tipranavir (Aptivus®), triazolam (when taken by mouth) (Halcion®), verapamil (Calan®, Covera-HS®, Isoptin®, Tarka®), voriconazole (when taken by mouth or when administered by injection) (Vfend®), warfarin (Coumadin®)

- This is **not** a complete list of medicines that could interact with OLYSIO™. Ask your healthcare provider or pharmacist i you are not sure if your medicine is one that is listed above.

- Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

What are the most common side effects of OLYSIO™?

- The most common side effects of OLYSIO™ when used in combination with peginterferon alfa and ribavirin include skin rash, itching, nausea.

- Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

- These are not all of the possible side effects of OLYSIO™. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Patient Information for more details.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; general industry conditions including trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

Media contacts:
Craig Stoltz
Phone: (609) 730-2823

Ronan Collins
Phone: +47 488 42 500

Investor contacts:
Stan Panasewicz
Phone: (732) 524-2524

Louise Mehrotra
Phone: (732) 524-6491