NEWS RELEASE

Janssen Submits Supplemental New Drug Application to U.S. FDA for All-Oral, Once-Daily OLYSIO® (Simeprevir) in Combination with Sofosbuvir

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TITUSVILLE, N.J. - July 23, 2015 - Janssen Therapeutics, Division of Janssen Products, LP (Janssen), today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to update the label for once-daily, all-oral OLYSIO® (simeprevir). OLYSIO® is a hepatitis C virus (HCV) NS3/4A protease inhibitor, currently approved for use with sofosbuvir for adults with genotype 1 chronic hepatitis C (CHC) infection as a 12-week treatment for patients without cirrhosis or a 24-week treatment regimen for patients with cirrhosis. Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor marketed by Gilead Sciences, Inc.

OLYSIO® was approved in November 2014 in combination with sofosbuvir based on the Phase 2 COSMOS clinical trial. This sNDA is based on results from the Phase 3 OPTIMIST-1 and OPTIMIST-2 trials, which evaluated 12 and eight weeks of therapy for treatment-naïve and treatment-experienced genotype 1 CHC adult patients without cirrhosis, and 12 weeks of therapy for treatment-naïve and treatment-experienced genotype 1 CHC adult patients with cirrhosis.

"OLYSIO® has contributed significantly to the care of people living with hepatitis C. The availability of multiple treatment options is important to help offer an opportunity for cure, and we believe OLYSIO® will continue to play a meaningful role going forward," said Richard Nettles, M.D., vice president, Medical Affairs, Janssen Therapeutics. "We're pleased to submit the data from the Phase 3 OPTIMIST trials, which adds to the body of clinical information about this combination in patients with and without cirrhosis."

Results from the OPTIMIST trials were presented in April 2015 at The International Liver Congress&#8482 2015 of the European Association for the Study of the Liver (EASL) in Vienna.

About the OPTIMIST Trials

OPTIMIST-1 is a Phase 3, randomized, open-label trial to investigate the efficacy and safety of the all-oral regimen of simeprevir and sofosbuvir (SMV/SOF) among treatment-naive and treatment-experienced genotype 1 CHC patients without cirrhosis. The primary study endpoint is sustained virologic response (SVR) at 12 weeks after treatment (SVR12) with 12 and eight weeks of treatment with SMV/SOF versus a historical control (patients previously treated with approved regimens containing a direct-acting antiviral, pegylated interferon and ribavirin).

- Ninety-seven (97) percent of patients treated with SMV/SOF for 12 weeks (n=150/155) achieved SVR12, which was superior to the SVR12 rate of 87 percent among the historical control.
    - SVR12 rates of 100 percent were seen among patients with IL28B CC genotype (n=43/43) and those with baseline NS5A and NS3 Q80K polymorphisms (n=9/9).
- Patients treated with eight weeks of SMV/SOF achieved an SVR12 rate of 83 percent (n=128/155), which was not superior to the SVR12 rate of 83 percent in the historical control.
    - High SVR12 rates were seen among patients with baseline HCV RNA < 4 million IU/mL (96 percent; n=46/48), IL28B CC genotype (93 percent; n=38/41), patients with genotype 1b CHC (92 percent; n=36/39) and patients without baseline NS5A and Q80K polymorphisms (89 percent; n=78/88).
- The most frequently reported adverse events in the 12- and eight-week treatment arms were headache (14 and 17 percent, respectively), fatigue (12 and 15 percent, respectively) and nausea (15 and 9 percent, respectively).

OPTIMIST-2 is a Phase 3, open-label, single-arm trial to investigate the efficacy and safety of SMV/SOF in treatment-naive and treatment-experienced genotype 1 CHC patients with cirrhosis. The primary endpoint is SVR12 with SMV/SOF versus a historical control.

- Twelve (12) weeks of treatment with SMV/SOF resulted in SVR12 rates of 84 percent (n=86/103), which was superior to the SVR12 rate of 70 percent in the historical control.
- Higher SVR12 rates were seen in patients with baseline NS5A polymorphisms with or without NS3 Q80K polymorphisms (100 percent; n=13/13), patients with albumin ≥4 g/dL (94 percent; n=47/50) and treatment-naïve patients (88 percent; n=44/50).
- The most common adverse events were fatigue (20 percent), headache (20 percent) and nausea (11 percent).

About Hepatitis C

Hepatitis C is a blood-borne infectious disease of the liver that affects approximately 2.7 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® (simeprevir) is an NS3/4A protease inhibitor which has been developed by Janssen Sciences Ireland UC in collaboration with Medivir AB.

In November 2013, OLYSIO® was initially approved by the U.S. FDA, and in May 2014, it was granted marketing authorization by the European Commission. Subsequent marketing authorizations have followed in several other countries around the world. Indications vary by market.

Janssen is responsible for the global clinical development of OLYSIO® and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB retains marketing rights for OLYSIO® in these countries under the marketing authorization held by Janssen-Cilag International NV.

About the Janssen HCV Development Program

The goal of the Janssen HCV clinical development program is to provide physicians with multiple treatment options in order to offer patients the best possible chance of achieving a cure. Ongoing studies focus on the investigation of the NS3/4A protease inhibitor simeprevir in a number of different treatment combinations and HCV patient populations, including those who are difficult to cure. Following the acquisition of Alios BioPharma by Johnson & Johnson in November 2014 and the recent collaboration with Achillion Pharmaceuticals Inc., the Janssen HCV pipeline includes AL-335, a uridine based nucleotide analog; AL-516, a guanosine-based nucleotide analog NS5B polymerase inhibitor; odalasvir (ACH-3102), an NS5A inhibitor; ACH-3422, a nucleotide pro-drug of a uridine analog; and sovaprevir, a protease inhibitor. These compounds are being developed with the express intent of targeting critical steps of the HCV virus replication cycle with the potential of delivering new treatment options for patients.

What is OLYSIO®?

- OLYSIO® is a prescription medicine used with other antiviral medicines to treat chronic (lasting a long time) hepatitis C infection in adults. OLYSIO® should not be taken alone. It is not known if OLYSIO® is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about OLYSIO®?

- If you are pregnant, or plan to become pregnant, talk with your healthcare provider before taking OLYSIO®. It is not known if OLYSIO® will harm your unborn baby. Also read the Medication Guides for peginterferon alfa (Peg-IFN-alfa) and ribavirin (RBV) if your healthcare provider prescribes these medications for you in combination with OLYSIO®.
    - Females must use an effective form of birth control during treatment with OLYSIO®. Talk with your healthcare provider about birth control methods that you may use during treatment with OLYSIO®.
- OLYSIO® combination treatment with sofosbuvir (Sovaldi®) may result in slowing of the heart rate (pulse) along with other symptoms when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems.
  If you are taking OLYSIO® with sofosbuvir and amiodarone and you get any of the following symptoms, or if you have a slow heart rate call your healthcare provider right away:
    - Fainting or near-fainting
    - Dizziness or lightheadedness
    - Weakness, extreme tiredness
    - Chest pain, shortness of breath
    - Confusion or memory problems
- OLYSIO® may cause severe liver problems in some patients.
  Your healthcare provider may do blood tests to check your liver function during treatment with OLYSIO®.
  Your healthcare provider may tell you to stop taking OLYSIO® if you develop signs and symptoms of liver problems.
  Tell your healthcare provider right away if you develop any of the following symptoms, or if they worsen during treatment with OLYSIO®:
    - tiredness
    - weakness
    - loss of appetite
    - nausea and vomiting
    - yellowing of your skin or eyes
    - color changes in your stools
- OLYSIO® combination treatment 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 combination treatment with OLYSIO®.
    - 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)

- You should not take OLYSIO® alone. OLYSIO® should be used together with other medicines 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 ever taken any medicine to treat hepatitis C virus infection
- 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 (when taken by mouth or given by injection, where applicable): amiodarone (Cordarone®, Nexterone®, 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, 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 (Diflucan®), fosamprenavir (Lexiva®), indinavir (Crixivan®), itraconazole

(Sporanox®, Onmel®), ketoconazole (Nizoral®), lopinavir (Kaletra®), lovastatin (Advicor®, Altoprev®, Mevacor®), mexiletine (Mexitil®), midazolam, 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 (Oxtellar XR&#8482,Trileptal®), phenobarbital (Luminal®), phenytoin (Dilantin®, Phenytek®), pitavastatin (Livalo®), posaconazole (Noxafil®), pravastatin (Pravachol®), propafenone (Rythmol SR®), quinidine (Nuedexta®, Duraquin®, Quinaglute®), rifabutin (Mycobutin®), rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®), 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, tadalafil (Adcirca®, Cialis®), telithromycin (Ketek®), tipranavir (Aptivus®), triazolam (Halcion®), verapamil (Calan®, Covera HS®, Isoptin®, Tarka®), voriconazole (Vfend®).

- This is not a complete list of medicines that could interact with OLYSIO®. Ask your healthcare provider or pharmacist if 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 possible side effects of OLYSIO®?

- The most common side effects in combination with Peg-IFN-alfa and RBV are skin rash, itching and nausea.
- The most common side effects in combination with sofosbuvir are tiredness, headache and 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.

When taking OLYSIO® in combination with Peg-IFN-alfa and RBV, you should also read those Medication Guides. When taking OLYSIO® in combination with sofosbuvir, you should also read its Patient Information leaflet.

Please see **full Prescribing Information** and **Patient Information** for more details.

About Janssen Therapeutics

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in HIV, hepatitis C and other infectious diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Headquartered in Titusville, New Jersey, Janssen Therapeutics, Division of Janssen Products, LP, is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Visit **www.JanssenTherapeutics.com** for more information and follow us on Twitter at @JanssenUS.

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 Products, LP and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; uncertainty of continued commercial success; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. 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 28, 2014, including in Exhibit 99 thereto, and the company's 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.

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