OLYSIO® (simeprevir) Gains Additional FDA Approval as Once-Daily, All-Oral Interferon- and Ribavirin-Free Treatment Option in Combination with Sofosbuvir for Adults with Genotype 1 Chronic Hepatitis C Infection

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TITUSVILLE, N.J. - November 5, 2014 - Janssen Therapeutics, Division of Janssen Products, LP (Janssen) announced the U.S. Food and Drug Administration (FDA) has approved OLYSIO® (simeprevir), a hepatitis C virus (HCV) NS3/4A protease inhibitor, in combination with sofosbuvir as an all-oral, interferon- and ribavirin-free treatment option for genotype 1 chronic hepatitis C (CHC) infection in adult patients as part of a combination antiviral treatment regimen. Sofosbuvir is an HCV nucleotide analog NS5B polymerase inhibitor developed by Gilead Sciences, Inc.

HCV is a blood-born infectious disease of the liver that affects an estimated 3.2 million people in the U.S.[1] Approximately 75 to 85 percent of people who become infected with HCV develop chronic infection.[2] Most persons with CHC infection are asymptomatic, which means they do not show symptoms of the disease.[3] When left untreated, CHC infection may cause significant liver damage, including cirrhosis, which is severe scarring of the liver. CHC may also increase the risk of developing complications from cirrhosis, which may include liver failure.[4]

Data supporting the OLYSIO® and sofosbuvir combination regimen are from the COSMOS study, an open-label, randomized Phase 2 clinical trial that investigated the efficacy and safety of 12 or 24 weeks of OLYSIO® (150 mg once daily) in combination with sofosbuvir (400 mg once daily) with or without ribavirin in HCV genotype 1 chronically infected treatment-naïve and treatment-experienced adult patients with compensated liver disease.

"It's a very encouraging time for patients with chronic hepatitis as the advent of new direct-acting treatment combinations, like OLYSIO® plus sofosbuvir offer all-oral, interferon- and ribavirin-free treatment options," said Eric Lawitz, M.D., primary investigator for the COSMOS clinical study, and vice president, Scientific and Research Development, The Texas Liver Institute and professor of medicine, University of Texas Health Science Center. "The availability of multiple treatment options is important to physicians and patients so optimal treatment decisions can be made, given the complexity of the disease and diversity of patient population."
"I lived with hepatitis C for nearly thirty years," said Norman Walsh, a COSMOS clinical trial patient. "I will never forget the moment that my clinical trial healthcare team told me the news following my treatment with the combination of OLYSIO® and sofosbuvir. I was elated, relieved - and cured."*

OLYSIO® in Combination with Sofosbuvir in HCV Adult, Genotype 1 Patients
The recommended treatment duration of OLYSIO® with sofosbuvir is 12 weeks for patients without cirrhosis or 24 weeks for patients with cirrhosis.

The data for this expanded indication are based on two cohorts in the COSMOS study, published in The Lancet. Cohort 1 included prior non-responder patients (patients who failed prior interferon-based therapy) with no to moderate liver fibrosis (defined as METAVIR F0 to F2 scores), and Cohort 2 included treatment-naïve patients (patients who have not received other treatments previously) and prior non-responder patients to peginterferon alfa and ribavirin near cirrhosis (METAVIR F3) and with cirrhosis (METAVIR F4). METAVIR scores measure the severity or stage of liver fibrosis, from early to advanced.

In pooled analyses of both cohorts, 95 percent of patients (20/21) with METAVIR F0-F3 receiving 12 weeks of OLYSIO® with sofosbuvir achieved sustained virologic response (SVR12) or cure, the absence of HCV detected in the blood 12 weeks after the end of treatment. Viral relapse occurred in 5 percent (1/21) and 0 percent (0/20) of patients with METAVIR F0-F3 after 12 or 24 weeks of combination therapy, respectively. Regardless of whether patients were treatment-naïve or treatment-experienced, 86 percent of patients (6/7) with METAVIR F4 receiving 12 weeks of OLYSIO® in combination with sofosbuvir achieved SVR12, while 100 percent of patients (10/10) with cirrhosis who were treated with the combination for 24 weeks achieved SVR12. Viral relapse occurred in 14 percent (1/7) and 0 percent (0/10) of patients with cirrhosis after 12 or 24 weeks of combination therapy, respectively.

For all patients in the COSMOS trial (treatment-naïve and treatment-experienced, METAVIR F0-F4), 93 percent (26/28) achieved SVR12 after 12 weeks and 97 percent (30/31) achieved SVR12 after 24 weeks of treatment. Viral relapse occurred in 7 percent of patients (2/28) after 12 weeks and 0 percent of patients (0/30) after 24 weeks of treatment overall.

In the COSMOS trial, the most common (> 10 percent) adverse reactions reported during 12 weeks of treatment with OLYSIO® in combination with sofosbuvir without ribavirin were fatigue (25 percent), headache (21 percent), nausea (21 percent), insomnia (14 percent) and pruritus (11 percent). Rash and photosensitivity were reported in 11 percent and 7 percent of patients, respectively. During 24 weeks of treatment with OLYSIO® in combination with sofosbuvir, dizziness (16 percent), and diarrhea (16 percent) were also commonly reported.

Prior to initiation of treatment with OLYSIO® with sofosbuvir, screening patients infected with HCV genotype 1a for the presence of virus with the NS3 Q80K polymorphism is not strongly recommended but may be considered.

Janssen is continuing its clinical development program for OLYSIO®, including Phase 3 study commitments. For more information please visit www.clinicaltrials.gov.

"We're pleased that an interferon-free, ribavirin-free OLYSIO®-based combination is now approved in the United States for patients with genotype 1 chronic hepatitis C infection. The availability of multiple treatment options is important to help offer an opportunity for cure and we believe OLYSIO® will play a meaningful role in this respect," said Gaston Picchio, PhD., Hepatitis disease area leader, Janssen Research & Development, LLC. "We're passionate about finding new treatment options for patients living with hepatitis C worldwide and will continue to pursue innovative approaches to help address this disease."

Access and Support for OLYSIO®
Janssen partners with a variety of stakeholders to support patient access and compliance to medicines. A substantial part of this effort is working closely with public and private payers to ensure that patients who need OLYSIO® can obtain access to it.

For patients, Janssen offers OLYSIO® Support, a comprehensive support program designed to assist in the HCV treatment journey so that they, their caregivers and their healthcare providers can help them focus on treatment. OLYSIO® Support provides benefit verifications, assistance with the prior authorization process, and information about a variety of affordability programs, including those for patients with commercial insurance, federally-funded insurance or no insurance coverage.

Eligible patients with commercial insurance coverage for OLYSIO® may pay only $5 per fill with the OLYSIO® Savings Card. This is subject to a $50,000 annual maximum benefit or 12 months from the card activation date, whichever comes first. For more information about OLYSIO® Support, visit www.OLYSIO.com or call 1-855-5-OLYSIO (1-855-565-9746), 8 a.m. - 8 p.m. (EST), Monday through Friday.

"The approval of OLYSIO® in combination with sofosbuvir is welcome news for people living with chronic hepatitis C infection and their families," said Gloria Searson, ACSW, founder and president, Coalition on Positive Health Empowerment (COPE). "As an organization focused on serving people trying to make sense of their HCV diagnosis, we're encouraged by the work Janssen is doing to provide new treatment options and support programs to help patients navigate their journey."**

About OLYSIO® (simeprevir)
OLYSIO® is an HCV NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment of CHC infection as a component of a combination antiviral treatment regimen.

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 in September 2013 in Japan, in November 2013 in Canada and the U.S., in March 2014 in Russia, and in July 2014 in Mexico and Australia. In May 2014 simeprevir was granted marketing authorization by the European Commission (EC) (indications vary by market).

For additional information about OLYSIO®, please visit www.OLYSIO.com.

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 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®, 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 XRTM,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 Pharmaceutical Companies
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in hepatitis C, HIV 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.

** Norman Walsh is a patient representative. Individual results may vary.*
***Janssen has provided funding to the Coalition on Positive Health Empowerment for educational and support initiatives benefiting hepatitis C patients and their families.*

(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, Janssen Research & Development, LLC 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 healthcare products and services; changes to laws and regulations and domestic and foreign healthcare reforms; and general industry conditions including trends toward healthcare 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 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.)

[1]Center for Disease Control and Prevention. "Hepatitis C FAQs for the Public." Available at: http://www.cdc.gov/hepatitis/c/cfaq.htm. Accessed October 2014.

[2]World Health Organization (WHO). "Hepatitis C." Available at: www.who.int/csr/disease/hepatitis/Hepc.pdf. Accessed October 2014.

[3]National Institute of Health, Medline Plus Dictionary. "Hepatitis C." Available at: http://www.nlm.nih.gov/medlineplus/ency/article/000284.htm. Accessed October 2014.

[4]World Health Organization (WHO). "Hepatitis C." Available at: www.who.int/csr/disease/hepatitis/Hepc.pdf. Accessed October 2014.

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