

TITUSVILLE, N.J., Nov. 22, 2013 /PRNewswire/ -- Janssen Therapeutics, Division of Janssen Products, LP (Janssen), announced today the U.S. Food and Drug Administration (FDA) has approved OLYSIO™ (simeprevir), an NS3/4A protease inhibitor, 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. OLYSIO

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may benefit patients with chronic hepatitis C, including those who are treatment naive or who have failed prior interferon-based therapy.

Chronic hepatitis C is a blood-borne infectious disease of the liver that affects approximately 3.2 million people in the United States.

OLYSIO™ works by blocking the viral protease enzyme that enables the hepatitis C virus (HCV) to replicate in host cells. The goal of treatment for chronic hepatitis C is cure, also known as sustained virologic response (SVR), which is defined as undetectable levels of HCV in the patients' blood 12 to 24 weeks after the end of treatment. For treatment-naive and prior-relapser patients, a fixed treatment regimen of 12 weeks of OLYSIO™ combined with 24 weeks of pegylated interferon and ribavirin is recommended. For prior partial- and null-responder patients, a treatment regimen of 12 weeks of OLYSIO

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combined with 48 weeks of pegylated interferon and ribavirin is recommended.

"Given the complexity of the condition, OLYSIO™ was studied in a number of different patient populations, including individuals who have relapsed or failed to respond to previous treatments," said Douglas Dieterich, M.D., Professor of Medicine in the Division of Liver Diseases, Mount Sinai School of Medicine, and OLYSIO™ clinical trial investigator. "The FDA approval of OLYSIO

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is an important milestone for people living with chronic hepatitis C as it means that patients have a new treatment option with the potential to cure this challenging disease."

OLYSIO™ is a prescription medicine used with other antiviral medicines, pegylated interferon and ribavirin, to treat genotype 1 chronic 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

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is safe and effective in children under 18 years of age.

The New Drug Application (NDA) filed by Janssen Research & Development, LLC, for OLYSIO

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was based in part on efficacy and safety results from three pivotal Phase 3 studies – QUEST-1 and QUEST-2 in treatment-naive patients and PROMISE in patients who have relapsed after prior interferon-based treatment – as well as data from the Phase 2b ASPIRE study in prior non-responder patients. Each of the studies evaluated OLYSIO

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dosed once daily in combination with pegylated interferon and ribavirin versus treatment with placebo plus pegylated interferon and ribavirin.

Results from a pooled analysis of QUEST-1 and QUEST-2 demonstrated that 80 percent of treatment-naive patients in the group receiving OLYSIO™ achieved sustained virologic response 12 weeks after the end of treatment (SVR12), compared with 50 percent of patients in the placebo groups. In PROMISE, 79 percent of prior-relapser patients in the simeprevir group of the study achieved SVR12 compared with 37 percent of patients in the placebo group. Results from ASPIRE demonstrated that use of OLYSIO

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led to sustained virologic response 24 weeks after the end of treatment (SVR24) in 65 percent of prior partial-responder patients and 53 percent of prior-null responder patients compared with 9 percent and 19 percent of prior partial- and null-responder patients in the placebo groups, respectively.

In the QUEST-1 and QUEST-2 studies, among genotype 1a treatment-naive patients receiving OLYSIO™ who had the Q80K polymorphism (a naturally occurring variation in the HCV NS3/4A protease enzyme), 58 percent achieved SVR12 versus 84 percent of patients without the Q80K

polymorphism. In the placebo arm, 52 percent of patients with the Q80K polymorphism achieved SVR12. In the PROMISE study, among prior-relapser patients with the Q80K polymorphism who received OLYSIO™, 47 percent achieved SVR12 versus 78 percent of patients without the polymorphism. In the placebo arm, 30 percent of patients with the Q80K polymorphism achieved SVR12.

"As an advocate working with the hepatitis C community, I'm pleased to know that Janssen has been working to make sure OLYSIO™ will be reasonably priced and available to the patients who need it," said Sue Simon, President of the Hepatitis C Association. "It is notable that in addition to introducing a new treatment option for patients, Janssen is establishing comprehensive programs to support and assist patients in their treatment journey."

Janssen has launched OLYSIO™ Support, a comprehensive support program designed in partnership with the HCV community to assist in the hepatitis C treatment journey so that patients and caregivers – and their healthcare providers – can focus on treatment. To register for OLYSIO™ Support or for additional information, please visit [OLYSIO.com](http://OLYSIO.com).

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

Janssen is responsible for the global clinical development of OLYSIO™ and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB will retain marketing rights for OLYSIO™ in these countries under the marketing authorization held by Janssen-Cilag International NV. The treatment was approved in September 2013

in Japan under the trade name SOVRIAD™

and in November 2013 in Canada

under the trade name GALEXOS

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for the treatment of genotype 1 hepatitis C. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013

by Janssen-Cilag International NV seeking approval of OLYSIO

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for the treatment of genotype 1 or genotype 4 chronic hepatitis C. To date, more than 3,700 patients have been treated with OLYSIO

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in clinical trials.

For additional information about OLYSIO™, please visit [www.OLYSIO.com](http://www.OLYSIO.com)

## **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.

## **IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know and who should not take OLYSIO?**

- 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®), 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 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 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](#) 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 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](http://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. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Therapeutics, Inc. 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, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; impact of business combinations; 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; 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 Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. 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. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

*NOTE:* Janssen Therapeutics, Division of Janssen Products, LP, provides support to the Hepatitis C Association for initiatives benefitting individuals living with hepatitis C.

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# **OLYSIO™ (simeprevir) Receives FDA Approval for Combination Treatment of Chronic Hepatitis C**

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