# OLYSIO™ (SIMEPREVIR) APPROVED FOR COMBINATION TREATMENT OF CHRONIC HEPATITIS C INFECTION IN GENOTYPE 1 INFECTED ADULTS WITH COMPENSATED LIVER DISEASE

janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

**QUEST-1 and QUEST-2 Studies**
## TREATMENT-NAÏVE PATIENTS
CLICK HERE FOR MORE INFORMATION

**PROMISE Study**
## PRIOR-RELAPSER PATIENTS
CLICK HERE FOR MORE INFORMATION

**ASPIRE Study**
## NON-RESPONDER PATIENTS
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## ABOUT OLYSIO™ (simeprevir)

- OLYSIO™ 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.

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

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IMPORTANT SAFETY INFORMATION

004504-131011

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## QUEST-1 and QUEST-2 Studies
## Treatment-Naïve Patients

Primary efficacy and safety results from a pooled analysis of QUEST-1 and QUEST-2 data demonstrated that use of OLYSIO™ led to sustained virologic response 12 weeks after the end of treatment (SVR12) in 80 percent of treatment-naïve genotype 1 chronic hepatitis C adult patients with compensated liver disease, including cirrhosis, when administered once daily with pegylated interferon and ribavirin, compared to 50 percent of patients treated with placebo administered once daily with pegylated interferon and ribavirin.

Among genotype 1a treatment-naïve patients with the Q80K polymorphism, 58 percent achieved SVR12 when treated with OLYSIO™ administered once daily with pegylated interferon and ribavirin versus 84 percent of patients without the polymorphism, compared to 52 percent and 43 percent of patients treated with placebo, respectively.

QUEST-1 and QUEST-2 are global, Phase 3, randomized, double-blind, placebo controlled clinical trials. In the QUEST-1 and QUEST-2 trials, 394 and 391 patients, respectively, were randomized to receive one 150 mg capsule of OLYSIO™ or placebo once daily plus pegylated interferon and ribavirin for 12 weeks, followed by pegylated interferon and ribavirin alone, for either 12 or 36 weeks.


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## PROMISE Study
## Prior-Relapser Patients

Primary efficacy and safety results from PROMISE demonstrated that use of OLYSIO™ led to sustained virologic response 12 weeks after the end of treatment (SVR12) in 79 percent of prior-relapser genotype 1 chronic hepatitis C adult patients with compensated liver disease, including cirrhosis, when administered once daily with pegylated interferon and ribavirin, compared to 37 percent of patients treated with placebo administered once daily with pegylated interferon and ribavirin.

Among genotype 1a prior-relapser patients with the Q80K polymorphism, 47 percent achieved SVR12 versus 78 percent of patients without the polymorphism, compared to 30 percent and 26 percent of patients treated with placebo, respectively.

PROMISE is a global, Phase 3, randomized, double-blind, placebo-controlled clinical trial. In the PROMISE trial, 393 patients were randomized to receive one 150 mg capsule of OLYSIO™ or placebo once daily plus pegylated interferon and ribavirin for 12 weeks, followed by pegylated interferon and ribavirin alone for either 12 or 36 weeks.

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## ASPIRE Study Non-Responder Patients

Primary efficacy and safety results from ASPIRE demonstrated that use of OLYSIO™ for 12 weeks led to sustained virologic response 24 weeks after the end of treatment (SVR24) in genotype 1 chronic hepatitis C adult patients with compensated liver disease, including cirrhosis, when administered once daily with pegylated interferon and ribavirin. In patients treated with 150 mg of OLYSIO™ for 12 weeks, 77 percent of prior relapsers, 65 percent of prior partial responders and 53 percent of prior null responders achieved SVR24 compared to 37 percent, 9 percent and 19 percent of patients treated with placebo administered once daily with pegylated interferon and ribavirin, respectively. In a pooled analysis of patients treated with 100 mg or 150 mg simeprevir for 12 weeks, 83 percent of prior relapsers, 67 percent of prior partial responders and 45 percent of prior null responders achieved SVR24.

ASPIRE is an international, Phase 2b, randomized, double-blind, placebo-controlled study in treatment experienced patients. In the ASPIRE trial, 396 treatment-experienced patients received either 100 or 150 mg of once-daily OLYSIO™ for 12, 24 or 48 weeks plus pegylated interferon and ribavirin for 48 weeks.


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## 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®), 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 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, including Patient Information for more details.**

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