

Olysio® (simeprevir) – Drug discontinuation

- **Janssen announced** the discontinuation of **Olysio (simeprevir)** due to a significant decline in utilization and the availability of effective therapies, such as pangenotypic combination regimens, which address the current medical need in treating hepatitis C virus (HCV) infection.
 - The discontinuation was not due to any safety, efficacy or quality issues.
 - Moreover, Janssen will voluntarily withdraw the New Drug Application for Olysio in the U.S. and product will no longer be available, effective May 25, 2018.
- Olysio, an HCV NS3/4A protease inhibitor, is indicated for the treatment of adults with chronic HCV infection in combination with **Sovaldi® (sofosbuvir)** in patients with HCV genotype 1 without cirrhosis or with compensated cirrhosis and in combination with peginterferon alfa (**Pegasys®**, **Peg-Intron®**) and **ribavirin** in patients with HCV genotype 1 or 4 without cirrhosis or with compensated cirrhosis.
 - **Incivek® (telaprevir)** and **Victrelis® (boceprevir)** were previously approved HCV NS3/4A protease inhibitors that were discontinued in 2014 and 2015, respectively, for business reasons.
- Healthcare professionals are advised not to initiate new patients on Olysio.
- Patients who are currently taking Olysio should complete their course of therapy in consultation with their healthcare provider. For patients who are unable to complete a full course of therapy, Janssen recommends healthcare providers refer to local guidelines on the treatment of hepatitis C.
- Examples of currently available pangenotypic combination regimens indicated to treat HCV include **Epclusa® (sofosbuvir/velpatasvir)**, **Mavyret™ (glecaprevir/pibrentasvir)**, and **Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)**. Refer to individual drug labels for indication information.
- For assistance or questions about the discontinuation of Olysio, contact Janssen at **1-800-526-7736**.