Olysio® Approved for Treating Chronic Hepatitis C

Janssen Therapeutics announced the U.S. Food and Drug Administration has approved Olysio® (simeprevir), a hepatitis C virus 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. Sofosbuvir is an HCV nucleotide analog NS5B polymerase inhibitor developed by Gilead Sciences, Inc.

Most individuals with CHC infection are asymptomatic. When left untreated, CHC infection may cause significant liver damage, including cirrhosis. CHC may also increase the risk of developing complications from cirrhosis, such as liver failure.

The data are based on two study cohorts, published in The Lancet. Cohort 1 included prior non-responder patients (i.e., patients who failed prior interferon-based therapy) with no to moderate liver fibrosis, and Cohort 2 included treatment-naive patients (i.e., patients who have not received other treatments previously) and prior non-responder patients to peginterferon alfa and ribavirin near cirrhosis and with cirrhosis.

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


Patient Support Program Helps Bring OFEV® to the United States

Boehringer Ingelheim Pharmaceuticals, Inc. has announced that OFEV® (nintedanib) capsules are now commercially available in the United States.

OFEV was approved by the U.S. Food and Drug Administration for the treatment of idiopathic pulmonary fibrosis (IPF), a rare and fatal lung disease that affects as many as 132,000 Americans who are typically men older than 65. It is the only kinase inhibitor approved to treat IPF.

To support the launch of OFEV, Boehringer Ingelheim has established OPEN DOORS™, a comprehensive patient support program that provides a broad range of financial and nursing support services. OPEN DOORS services and resources include:

- Access to support from specially trained nurses 24 hours per day, 7 days per week.
- Assistance in finding financial resources to support access to OFEV.
- Access to information about IPF and assistance in identifying local resources, such as support groups.

OFEV is commercially available through specialty pharmacy distributors, as well as a select network of pharmacies. The dedicated specialty pharmacy model is intended to provide one point of contact for efficient, reliable service and consistent product supply. Pharmacies offering OFEV were selected for their experience caring for patients with severe respiratory diseases. Selected pharmacies are positioned to offer additional services including respiratory therapy and oxygen.