Technivie® (ombitasvir/paritaprevir/ritonavir) – Expanded indication

- On February 27, 2017, the FDA approved AbbVie's Technivie (ombitasvir/paritaprevir/ritonavir), in combination with ribavirin for the treatment of patients with genotype 4 (GT4) chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis.
    - Previously, Technivie was approved only in patients without cirrhosis.
- Efficacy for the expanded indication of Technivie was based on the AGATE-I trial. This was an open-label study of 120 patients with GT4 chronic HCV infection with compensated cirrhosis treated with Technivie and ribavirin for 12 or 16 weeks. The primary endpoint was sustained virologic response 12 weeks after the end of treatment (SVR_{12}).
    - The SVR_{12} was 97% (57/59) for patients treated for 12 weeks.
    - Treatment for 16 weeks was not shown to further increase SVR_{12} rates.
- Technivie carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients co-infected with HCV and HBV.
- The most common adverse events (> 10%) with Technivie and ribavirin use in patients with compensated cirrhosis were fatigue, asthenia, headache, musculoskeletal pain, pruritus, insomnia/sleep disorder, skin reactions, mood disorders, nausea, dizziness and dyspnea.
- For patients without cirrhosis or with compensated cirrhosis, the recommended dose of Technivie is two tablets orally once daily (in the morning) with a meal in combination with ribavirin for 12 weeks.
    - Technivie may be administered without ribavirin in treatment-naïve patients without cirrhosis who cannot take or tolerate ribavirin.
    - Technivie is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C).
    - Refer to the ribavirin prescribing information for specific dosing instructions.