Onivyde® (irinotecan liposome injection) – New indication

- On February 13, 2024, Ipsen announced the FDA approval of Onivyde (irinotecan liposome injection), in combination with oxaliplatin, fluorouracil and leucovorin for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma.
    - Onivyde is not indicated as a single agent for the treatment of patients with metastatic pancreatic adenocarcinoma.
- Onivyde is also approved in combination with fluorouracil and leucovorin, for the treatment of adult patients with metastatic pancreatic adenocarcinoma after disease progression following gemcitabine-based therapy.
- The approval of Onivyde for the new indication was based on NAPOLI 3, a randomized, open-label, active-controlled study in 770 patients with metastatic pancreatic adenocarcinoma who had not previously received chemotherapy in the metastatic setting. Patients were randomized to receive: (1) NALIRIFOX: Onivyde + oxaliplatin + leucovorin + fluorouracil; or (2) Gem+NabP: Nab-paclitaxel + gemcitabine. Treatment continued until disease progression or unacceptable toxicity. The main efficacy measure was overall survival (OS). Additional efficacy measures were progression-free survival (PFS) and objective response rate (ORR).
    - Median OS was 11.1 months and 9.2 months for NALIRIFOX and Gem+NabP, respectively (hazard ratio [HR] 0.84, 95% CI: 0.71, 0.99; p = 0.0403).
    - Median PFS was 7.4 months and 5.6 months for NALIRIFOX and Gem+NabP, respectively (HR 0.70, 95% CI: 0.59, 0.85; p = 0.0001).
    - The ORR was 41.8% (95% CI: 36.8, 46.9) for NALIRIFOX vs. 36.2% (95% CI: 31.4, 41.2) for Gem+NabP.
- Onivyde carries a boxed warning for severe neutropenia and severe diarrhea.
- The most common adverse reactions (≥ 20%) with Onivyde in combination with oxaliplatin, fluorouracil and leucovorin were diarrhea, fatigue, nausea, vomiting, decreased appetite, abdominal pain, mucosal inflammation, constipation, and decreased weight. The most common laboratory abnormalities (≥ 10% Grade 3 or 4) were decreased neutrophils, decreased potassium, decreased lymphocytes, and decreased hemoglobin.
- When used in combination with oxaliplatin, fluorouracil and leucovorin for first-line treatment of pancreatic adenocarcinoma, the recommended dose of Onivyde is 50 mg/m^2 administered by intravenous infusion over 90 minutes every 2 weeks.
    - Refer to the Onivyde drug label for dosing for its other indication.