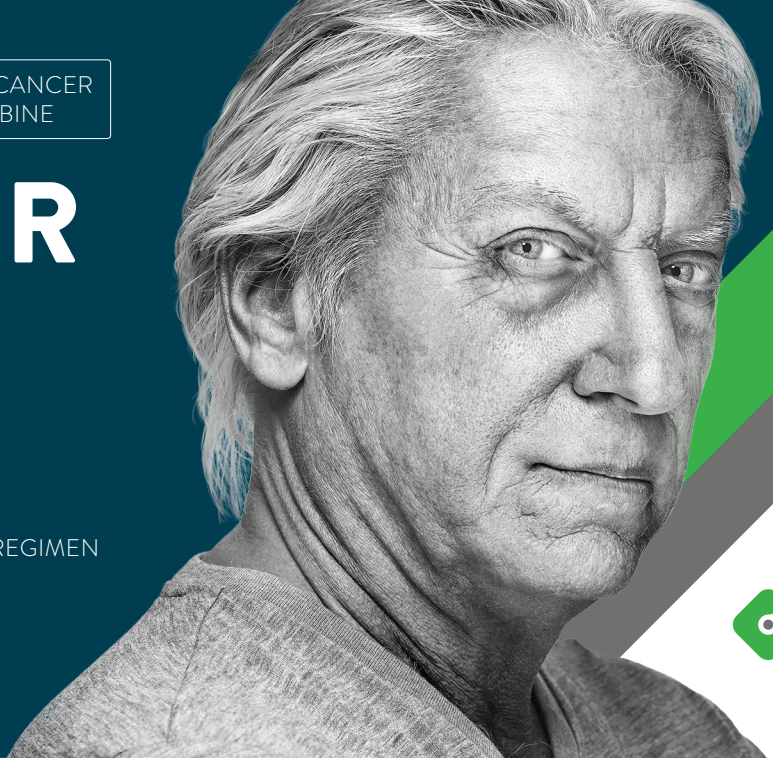
WHEN METASTATIC PANCREATIC CANCER (mPC) PROGRESSES ON GEMCITABINE

HELP YOUR PATIENTS FIGHT ON

DON'T MISS THE CHANCE TO CONSIDER **ONIVYDE® + 5-FU/LV**, THE #1 PRESCRIBED 2L REGIMEN AND ONLY FDA-APPROVED THERAPY FOR mPC PATIENTS AFTER GEMCITABINE[1]

Based on metastatic pancreatic cancer patients who have had at least 3 cycles of a gemcitabine-based regimen and did not have pancreatic cancer-related activity for 60 days prior to beginning an ONIVYDE® treatment regimen.

Actor portrayal



onivyde® (irinotecan liposome injection)

ADD A PROVEN TOOL TO YOUR PLAN FOR FIGHTING mPC[2]

- Proven in NAPOLI-1—a large phase 3 trial* in patients with mPC with disease progression after gemcitabine-based therapy[3,4]
- The most common serious adverse reactions (≥2%) of ONIVYDE® were diarrhea, vomiting, neutropenic fever or neutropenic sepsis, nausea, pyrexia, sepsis, dehydration, septic shock, pneumonia, acute renal failure, and thrombocytopenia

PRESCRIBED TO OVER 18,000 US PATIENTS[5] BY OVER 2,000 US HCPs[6] SINCE FDA APPROVAL

- ONIVYDE® + 5-FU/LV is the fastest-growing 2L regimen in mPC[7]
- Covered on over 400 health plans for appropriate patients[8†]

†Prior authorization may be required. Refer to your patient's health plan.

SHOWN TO EXTEND OVERALL SURVIVAL (OS)[2]

- Median OS: 6.1 months for ONIVYDE® + 5-FU/LV (95% CI: 4.8, 8.5) vs 4.2 months for 5-FU/LV alone (95% CI: 3.3, 5.3) log-rank p=0.014, HR: 0.68 meaning 32% reduction of risk of death

*NAPOLI-1 was a global, phase 3, randomized, open-label, multicenter trial in patients (N=417) with metastatic adenocarcinoma of the pancreas whose disease had progressed following gemcitabine-based therapy. Patients were initially randomized to receive ONIVYDE® (100 mg/m^2 every 3 weeks) or 5-FU/LV. After 63 patients were enrolled, a third arm, ONIVYDE® (70 mg/m^2 every 2 weeks) + 5-FU/LV, was added. Treatment was continued until disease progression or unacceptable toxicity. The primary endpoint was median OS. Additional efficacy endpoints were PFS and ORR.[2,4]

PFS=progression-free survival; ORR=objective response rate.

INDICATION

ONIVYDE® (irinotecan liposome injection) is indicated, in combination with fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Limitation of Use: ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE NEUTROPENIA and SEVERE DIARRHEA

- **Fatal neutropenic sepsis occurred in 0.8% of patients receiving ONIVYDE. Severe or life-threatening neutropenic fever or sepsis occurred in 3% and severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE in combination with 5-FU and LV. Withhold ONIVYDE for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment**
- **Severe diarrhea occurred in 13% of patients receiving ONIVYDE in combination with 5-FU/LV. Do not administer ONIVYDE to patients with bowel obstruction. Withhold ONIVYDE for diarrhea of Grade 2–4 severity. Administer loperamide for late diarrhea of any severity. Administer atropine, if not contraindicated, for early diarrhea of any severity**

Please see continued Important Safety Information, and accompanying full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATION

- ONIVYDE is contraindicated in patients who have experienced a severe hypersensitivity reaction to ONIVYDE or irinotecan HCl

WARNINGS AND PRECAUTIONS

- **Severe Neutropenia : See Boxed WARNING.** In patients receiving ONIVYDE/5-FU/LV, the incidence of Grade 3/4 neutropenia was higher among Asian (18/33 [55%]) vs White patients (13/73 [18%]). Neutropenic fever/neutropenic sepsis was reported in 6% of Asian vs 1% of White patients
- **Severe Diarrhea: See Boxed WARNING.** Severe and life-threatening late-onset (onset >24 hours after chemotherapy [9%]) and early-onset diarrhea (onset ≤24 hours after chemotherapy [3%], sometimes with other symptoms of cholinergic reaction) were observed
- **Interstitial Lung Disease (ILD):** Irinotecan HCl can cause severe and fatal ILD. Withhold ONIVYDE in patients with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation. Discontinue ONIVYDE in patients with a confirmed diagnosis of ILD
- **Severe Hypersensitivity Reactions:** Irinotecan HCl can cause severe hypersensitivity reactions, including anaphylactic reactions. Permanently discontinue ONIVYDE in patients who experience a severe hypersensitivity reaction
- **Embryo-Fetal Toxicity:** ONIVYDE can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE treatment

ADVERSE REACTIONS

- The most common adverse reactions (≥20%) were diarrhea (59%), fatigue/asthenia (56%), vomiting (52%), nausea (51%), decreased appetite (44%), stomatitis (32%), and pyrexia (23%)
- The most common Grade 3/4 adverse reactions (≥10%) were diarrhea (13%), fatigue/asthenia (21%), and vomiting (11%)
- Adverse reactions led to permanent discontinuation of ONIVYDE in 11% of patients receiving ONIVYDE/5-FU/LV; The most frequent adverse reactions resulting in discontinuation of ONIVYDE were diarrhea, vomiting, and sepsis
- Dose reductions of ONIVYDE for adverse reactions occurred in 33% of patients receiving ONIVYDE/5-FU/LV; the most frequent adverse reactions requiring dose reductions were neutropenia, diarrhea, nausea, and anemia
- ONIVYDE was withheld or delayed for adverse reactions in 62% of patients receiving ONIVYDE/5-FU/LV; the most frequent adverse reactions requiring interruption or delays were neutropenia, diarrhea, fatigue, vomiting, and thrombocytopenia
- The most common laboratory abnormalities (≥20%) were anemia (97%), lymphopenia (81%), neutropenia (52%), increased ALT (51%), hypoalbuminemia (43%), thrombocytopenia (41%), hypomagnesemia (35%), hypokalemia (32%), hypocalcemia (32%), hypophosphatemia (29%), and hyponatremia (27%)

DRUG INTERACTIONS

- Avoid the use of strong CYP3A4 inducers, if possible, and substitute non-enzyme inducing therapies ≥2 weeks prior to initiation of ONIVYDE
- Avoid the use of strong CYP3A4 or UGT1A1 inhibitors, if possible, and discontinue strong CYP3A4 inhibitors ≥1 week prior to starting therapy

USE IN SPECIFIC POPULATIONS

- **Pregnancy and Reproductive Potential:** See WARNINGS & PRECAUTIONS. Advise males with female partners of reproductive potential to use condoms during and for 4 months after ONIVYDE treatment
- **Lactation:** Advise nursing women not to breastfeed during and for 1 month after ONIVYDE treatment

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Boxed WARNING. For more information, visit ONIVYDE.com

References: 1. Ipsen data on file: IQVIA medical claims post-gemcitabine usage analysis, June 2018 - May 2019. **2.** ONIVYDE® [package insert]. Basking Ridge, NJ. Ipsen Biopharmaceuticals, Inc.; 2017. **3.** Data on file #1. Basking Ridge, NJ. Ipsen Biopharmaceuticals, Inc.; 2015. **4.** Wang-Gillam A, Li C-P, Bodoky G, et al. *Lancet*. 2016;387:545-557. **5.** Ipsen data on file. **6.** Ipsen data on file: IQVIA APLD medical claims 2015-2019. **7.** Ipsen data on file: Flatiron Health EHR data for metastatic pancreatic cancer patients, 2014-2019. **8.** Ipsen data on file: Zitter Policy & Access Tracking Tool, Q3 2019.

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Innovation for patient care

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