The Medical Letter®

on Drugs and Therapeutics

Volume 58 **June 6, 2016**

ISSUE No. 1496

IN THIS ISSUE

The Medical Letter®
on Drugs and Therapeutics

Volume 58 (Issue 1496) June 6, 2016

IN BRIEF

Liposomal Irinotecan (*Onivyde*) for Pancreatic Cancer

A liposomal formulation of irinotecan (*Onivyde* – Merrimack) has been approved by the FDA for use in combination with fluorouracil and leucovorin for treatment of metastatic pancreatic cancer that has progressed after gemcitabine-based therapy. A non-liposomal formulation of irinotecan (*Camptosar*, and generics) has been available in the US for many years. The liposomal carrier prolongs exposure to irinotecan and improves the cellular uptake and cytotoxic effect of the drug.[1]

FDA approval of liposomal irinotecan was based on the results of an open-label trial (NAPOLI-1) in 417 patients with metastatic pancreatic ductal adenocarcinoma whose disease progressed after gemcitabine-based therapy. Patients were randomized to receive either liposomal irinotecan alone, fluorouracil and leucovorin alone, or liposomal irinotecan in combination with fluorouracil and leucovorin. Median overall survival, the primary endpoint, was significantly longer with all three drugs (6.1 months), compared to fluorouracil and leucovorin alone (4.2 months) and liposomal irinotecan alone (4.9 months). The most frequent severe (grade 3 or 4) adverse effects of the liposomal irinotecan-containing regimen were neutropenia, diarrhea, vomiting, and fatigue.[2] Life-threatening diarrhea has also occurred in patients receiving the 3-drug combination.

Onivyde is available in 43 mg/10 mL single-dose vials. The recommended dosage is 70 mg/m^2 administered intravenously over 90 minutes every 2 weeks; leucovorin and fluorouracil should be administered after liposomal irinotecan. The recommended starting dose of *Onivyde* for patients who are homozygous for the UGT1A1*28 allele is 50 mg/m^2; the dose can be increased to 70 mg/m^2 as tolerated. The labeling specifies a number of dosage adjustments that should be made when adverse effects occur. One dose of *Onivyde* costs $4860.[3]

1. A Casadó et al. Formulation and in vitro characterization of thermosensitive liposomes for the delivery of irinotecan. J Pharm Sci 2014; 103:3127.
2. A Wang-Gillam et al. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. Lancet 2016; 387:545.
3. Approximate WAC for a patient with a 1.7 m^2 surface area. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. May 5, 2016. Reprinted with permission by First Databank, Inc. All rights reserved. ©2016. www.fdb-health.com/policies/drug-pricing-policy.

The Medical Letter® Vol. 58 (1496) June 26 2016

Subscription Services

Address:
The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:
Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:
To reproduce any portion of this issue, please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):
1 year - $129; 2 years - $232;
3 years - $345. $65 per year for students, interns, residents, and fellows in the US and Canada.
Reprints - $12 each.

Site License Inquiries:
E-mail: info@medicalletter.org
Call: 800-211-2769 ext. 315
Special rates available for bulk subscriptions.

Get Connected:

Copyright 2016. ISSN 1523-2859