

# The Medical Letter<sup>®</sup>

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### IN THIS ISSUE

In Brief: Liposomal Irinotecan (*Onivyde*) for Pancreatic Cancer ..... online only

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Volume 58 (Issue 1496)

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### 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.<sup>1</sup>

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.<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup>; the dose can be increased to 70 mg/m<sup>2</sup> as tolerated. The labeling specifies a number of dosage adjustments that should be made when adverse effects occur. One dose of *Onivyde* costs \$4860.<sup>3</sup>

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<sup>2</sup> 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](http://www.fdb-health.com/policies/drug-pricing-policy).

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