

# FDA approves new pancreatic cancer drug

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Agency says medication can be used in combination with others for advanced cases.

(HealthDay)—The U.S. Food and Drug Administration has approved a new drug called Onivyde as part of a treatment regimen for advanced pancreatic cancer.

Onivyde (irinotecan liposome injection) was approved to be used in combination with fluorouracil and leucovorin. The combination was approved for use in patients with advanced [pancreatic cancer](#) who were already treated with gemcitabine-based chemotherapy, the FDA said Thursday in a news release.

The approval was based on a study of more than 400 patients. All had experienced cancer growth despite gemcitabine-based chemotherapy. The new research included three treatment arms. Patients were randomly assigned to receive Onivyde with fluorouracil/leucovorin, Onivyde alone, or fluorouracil/leucovorin alone.

The researchers found that people treated with Onivyde plus fluorouracil/leucovorin lived an average of 6.1 months, compared to 4.2 months for those treated with only fluorouracil/leucovorin, the FDA said.

But, there was no survival benefit for patients who received Onivyde alone compared to those who received only fluorouracil/leucovorin, the findings showed.

The study also found that the average amount of time to tumor growth was 3.1 months for patients who received Onivyde plus fluorouracil/leucovorin compared to 1.5 [months](#) for those who received only fluorouracil/leucovorin.

The most common side effects of Onivyde were diarrhea, fatigue, vomiting, nausea, decreased appetite, inflammation in the mouth and fever, the researchers said.

The drug also led to low counts of infection-fighting cells (lymphopenia and neutropenia). The FDA also said that death due to sepsis—a severe inflammatory response triggered by infection—following neutropenia has been reported in [patients](#) taking Onivyde.

Onivyde's label carries a boxed warning about the risks of severe neutropenia and diarrhea. The [drug](#) is marketed by Merrimack Pharmaceuticals Inc., of Cambridge, Mass.

Nearly 49,000 new cases of pancreatic cancer will be diagnosed in the United States this year and there will be more than 40,500 deaths from the disease, according to the U.S. National Cancer Institute.

Pancreatic cancer is difficult to diagnose early and there are limited treatment options, especially when it has spread to other parts of the

body and surgery to remove the tumor is not possible, the FDA said in the news release.

**More information:** The U.S. National Cancer Institute has more about [pancreatic cancer](#).

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