

# FDA approves new therapy for pancreatic cancer patients

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Axial CT image with i.v. contrast. Macrocystic adenocarcinoma of the pancreatic head. Credit: public domain

Patients with advanced pancreatic cancer now have access to the new FDA approved drug, Onivyde, that produced significant overall survival rates in an international clinical study conducted in part by researchers at

HonorHealth Research Institute and the Translational Genomics Research Institute (TGen).

"Results from our clinical trial research showed a patient survival rate of nearly two more months without decreasing the quality of life compared to the other treatments tested, " said Gayle Jameson, principal investigator, NAPOLI-1 study and associate investigator, HonorHealth Research Institute. "Invariably pancreatic cancer progresses at some point and we don't have a universal standard of what to do next. In this disease, two months of survival is a game changer for treating advanced pancreatic cancer and gives patients hope."

Each year in the U.S., nearly 49,000 people are diagnosed with pancreatic cancer, and more than 39,000 patients die, making it the fourth leading cause of cancer death. Only about 1 in 4 patients survive more than one year after diagnosis, and less than 10 percent survive more than five years.

Onivyde, will be used as part of a combination regimen with a two-drug chemotherapy. It was approved to treat patients with pancreatic cancer that progressed after treatment with a different chemotherapy.

"As part of the team of medical researchers who studied the effectiveness of MM-398 plus 5-FU and leucovorin drug combination, we are thrilled that the FDA has approved the drug for use in patients throughout the nation," said Dr. Daniel D. Von Hoff, MD, FACP, global principal investigator of the NAPOLI-1 study, Chief Scientific Officer for HonorHealth Research Institute and Physician-In-Chief and Distinguished Professor at TGen.

The large, randomized clinical trial that evaluated the new drug, the NAPOLI-1 (NAnoliPOsomaL Irinotecan), was sponsored by Merrimack Pharmaceuticals. It evaluated patients enrolled at more than 100 sites in

North America, South America, Europe, Asia and Australia, including patients at HonorHealth Research Institute. The 417 patients in the study all had metastatic pancreatic cancer that was previously and treated with the traditional standard-of-care, gemcitabine-based therapy.

Symptoms of [pancreatic cancer](#) usually do not appear until the cancer is in its late stages, making it difficult to treat. Once the disease spreads to other parts of the body, most [patients](#) are not candidates for surgery and receive chemotherapy as their primary treatment.

**More information:** Patients seeking information about research studies may contact the HonorHealth Research Institute at 480-323-1339 or toll free at 1-877-273-3713, or email [clinicaltrials@honorhealth.com](mailto:clinicaltrials@honorhealth.com).

Provided by The Translational Genomics Research Institute

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