

New therapy for pancreatic cancer patients shows promising results

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A clinical trial conducted by researchers at the Virginia G. Piper Cancer Center Clinical Trials, a partnership between Scottsdale Healthcare and the Translational Genomics Research Institute (TGen), showed that a new drug called MM-398, given in combination with 5-fluorouracil (5FU) and leucovorin, produced a significant overall survival rate in patients with advanced, previously-treated pancreatic cancer.

The NAPOLI-1 (NAnoliPOsomaL Irinotecan) Phase 3 study—a final confirmation of a drug's safety and effectiveness—was conducted among [patients](#) with metastatic pancreatic cancer who previously received gemcitabine, which has been the standard-of-care therapy for such patients.

The study, sponsored by Merrimack Pharmaceuticals, evaluated 417 patients enrolled at more than 100 sites in North America, South America, Europe, Asia and Australia, including patients at the Virginia G. Piper Cancer Center at Scottsdale Healthcare. Merrimack expects to submit a New Drug Application this year to the U.S. Food and Drug Administration (FDA) for the MM-398 combination regimen.

"This demonstration of a survival benefit from the MM-398 plus 5-FU and leucovorin combination is particularly important given that we have very few treatment options for patients in this tough clinical setting," said Dr. Daniel D. Von Hoff, MD, FACP, global principal investigator of the NAPOLI-1 study, Chief Scientific Officer for Scottsdale Healthcare's Virginia G. Piper Cancer Center Clinical Trials and

Physician-In-Chief and Distinguished Professor at TGen. "The results of the NAPOLI-1 study are important because of the critical need to help patients with this devastating illness and move forward towards FDA approval."

The combination of MM-398 with 5-fluorouracil (5-FU) and leucovorin achieved an overall survival of 6.1 months, a 1.9 month improvement over the 4.2 month survival demonstrated by the control arm of 5-FU and leucovorin alone.

Each year in the U.S., nearly 46,000 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 only 6 percent survive more than five years.

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.

This study will be presented at the European Society for Medical Oncology World Conference on Gastrointestinal Cancer being held June 25-28 in Barcelona, Spain.

Provided by The Translational Genomics Research Institute

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