

Pancreatic cancer patient survival 'significantly higher' with nab-paclitaxel

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By all measures, the addition of nab-paclitaxel for the treatment of patients with advanced pancreatic cancer was superior to the survival for patients who received only gemcitabine, according to the results of a study led by the Translational Genomics Research Institute (TGen) and Scottsdale Healthcare, published today by *The New England Journal of Medicine*.

The study of 861 [patients](#), conducted at 151 community and academic centers in 11 nations, found that the 431 patients assigned nab-paclitaxel—in addition to the standard-of-care gemcitabine—had significantly improved overall survival, progression-free survival, and drug response rates than for the 430 assigned to gemcitabine alone.

"This large, randomized, international, phase 3 study showed that the nab-paclitaxel plus gemcitabine led to a significant improvement in survival at all time points," said Dr. Daniel D. Von Hoff, TGen Distinguished Professor and Physician-In-Chief, and Chief Scientific Officer for the Virginia G. Piper Cancer Center Clinical Trials at Scottsdale Healthcare, a partnership with TGen.

"The rate of survival was significantly higher in the nab-paclitaxel-gemcitabine group than in the gemcitabine group," said Dr. Von Hoff, lead author among the study's 23 co-authors and more than 130 researchers. He served as Principal Investigator of MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial), which included sites in North America, Europe and Australia.

Dr. Von Hoff, considered among the nation's leading authorities on [pancreatic cancer](#), also was the principal investigator for the first clinical trial of gemcitabine, the first therapy to show improvement in survival for patients with pancreatic cancer. The FDA approved gemcitabine in 1996.

On Sept. 6, the U.S. Food and Drug Administration (FDA) approved nab-paclitaxel (produced by Celgene Corporation under the brand name Abraxane) for use in advanced pancreatic cancer patients. Abraxane previously was approved by the FDA for use in the treatment of metastatic breast cancer (2005) and advanced lung cancer (2012).

While it is still uncertain exactly how Abraxane works, Abraxane wraps traditional chemotherapy, paclitaxel, in near-nano sized shells of albumin, a protein that the tumor could recognize as food. Once inside the tumor, the Abraxane may act like a "Trojan Horse" to release chemotherapy and kill the [cancer](#) cells.

Participants treated with Abraxane plus gemcitabine lived, on average, 1.8 months longer than those treated with gemcitabine alone, and they experienced a delay in tumor growth (progression-free survival) that was, on average, 1.8 months later than the participants who only received gemcitabine.

Of note, 35 percent of patients who also received Abraxane survived more than 1 year, a 59 percent increase over the 22 percent of those receiving only gemcitabine who survived more than 1 year. Also, more than twice as many patients (9 percent) who also received Abraxane survived more than 2 years, compared to those (4 percent) who only received gemcitabine.

"This a major breakthrough, but there is more work to be done. Building on these results, we are evaluating new targeted agents in combination

with the Abraxane/[gemcitabine](#) regimen," said Dr. Ramesh Ramanathan, Medical Director of the Virginia G. Cancer Center Clinical Trials at Scottsdale Healthcare, and MPACT principal investigator for the United States.

The most significant side effect from the addition of nab-paclitaxel was peripheral neuropathy, such as numbness in the hands and feet, although this occurred in only a small proportion of patients and was "rapidly reversible in most patients" by temporarily halting the drug and subsequently reducing its dosage. None of the patients experienced severe (grade 4) neuropathy.

The pancreas is a glandular organ behind the stomach that secretes enzymes to help digestion, and produces hormones, including insulin, which helps regulate blood-sugar metabolism.

"We are very grateful to the Seena Magowitz Foundation and to the Bedding Industry, which supported the research, leading to this important new survival-improving combination therapy," said Dr. Von Hoff. "We also appreciate the support of Stand Up To Cancer."

Provided by The Translational Genomics Research Institute

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