

CTCA at Western Regional Medical Center advances combination immunotherapy clinical trial

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Cancer Treatment Centers of America (CTCA) at Western Regional Medical Center (Western) in Goodyear, Arizona, has announced the launch of Phase II of the NivoPlus clinical trial, which combines the immunotherapeutic agent nivolumab with chemotherapy drugs irinotecan and capecitabine. The use of nivolumab is considered investigational in this study.

The NivoPlus clinical trial aims to enlist as many as 49 [patients](#). The Phase II portion of the study targets colorectal [cancer](#) with K-ras mutation and [pancreatic cancer](#). Phase II has begun enrolling patients and is anticipated to continue through 2016. Western's Phase Ib of the NivoPlus clinical trial study began in June 2015, when the first patient received [treatment](#). Other arms of this multi-faceted study treat patients with other immuno- and chemotherapy combinations to monitor NivoPlus' benefits in advanced kidney, uterine, non-small cell lung cancers, and other advanced cancer types.

"There is growing evidence that the use of immunotherapies like those in our NivoPlus [clinical trials](#) could enhance the ability to fight cancers," said Dr. Glen Weiss, Director of Clinical Research and Medical Oncologist, CTCA at Western. "We will be testing this new arm for patients with colorectal cancer with K-ras mutations and pancreatic cancer to determine its effectiveness and safety."

The addition of nivolumab is intended to activate the body's own immune system which may improve the results that might otherwise be achieved from chemotherapy alone. Nivolumab works by inhibiting a protein called PD-1, which otherwise blocks the body's immune system from attacking cancerous cells. Nivolumab was approved by the Food and Drug Administration in December 2014 for the [treatment of advanced melanoma](#) and on October 9, 2015 for patients with [previously treated metastatic non-small cell lung cancer](#).

"We are providing access to potential new treatments for patients with advanced-stage cancers who may have tried other treatment options," said Dr. Vivek Khemka, Medical Oncologist, CTCA Western and NivoPlus Principal Investigator. "By incorporating immunotherapy against cancer here at CTCA at Western, we are investigating other approaches to combat their disease."

In Phase I of clinical trials, researchers test a treatment in a small group of patients for the first time to evaluate its safety, determine a safe dosage range and identify side effects. In Phase II, the treatment is given to a larger group of patients to see if it is effective and to further evaluate its safety. This is a continuation of the third such combination immunotherapy and chemotherapy clinical trial launched in the past year by CTCA at Western.

Recent data reported in the New England Journal of Medicine^{1,2} and Lancet³ demonstrates promising results with antibody-based immunostimulatory therapy in treating melanoma, renal cell carcinoma, non-small cell lung cancer and [colorectal cancer](#). Data has also shown synergetic effects of utilizing cytotoxic chemotherapy in combination with [immunostimulatory therapy](#). The NivoPlus clinical trial will build upon this data by testing the treatment on additional cancer types.

CTCA investigators have been actively researching the impact of

immunotherapy, a topic prominently highlighted in 2015 at the annual conferences of both the American Association for Cancer Research (AACR) and the American Society of Clinical Oncologists (ASCO).

More information: References:

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3. Robert C, Ribas A, Wolchok JD, et al. Anti-programmed-death-receptor-1 treatment with pembrolizumab in ipilimumab-refractory advanced melanoma: a randomised dose-comparison cohort of a phase 1 trial. *Lancet* 2014;384(9948):1109-17.

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