

## Moffitt Cancer Center begins Phase I clinical trial of new immunotherapy

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Moffitt Cancer Center has initiated a phase I clinical trial for a new immunotherapy drug, ID-G305, made by Immune Design. Immunotherapy is a treatment option that uses a person's own immune system to fight cancer. It has several advantages over standard cancer therapies, including fewer side effects and an overall better tolerability. It tends to be most effective in patients who have smaller, localized tumors that have not spread to distant sites.

"This clinical trial is to assess ID-G305 and its ability to activate the immune system in patients with advanced stage melanoma, sarcoma, lung, ovarian, or <u>breast cancer</u>," said Amit Mahipal, M.D., M.P.H., medical director of Moffitt's Clinical Research Unit. "Our first patient in this trial is a metastatic sarcoma patient who has undergone two previous surgeries and one chemotherapy regimen."

ID-G305 is a cancer vaccine that is made up of two parts, a protein called NY-ESO-1 that is found in many different types of cancer, and an agent called GLAASTM developed by Immune Design. GLAASTM activates a type of cell called a dendritic cell that normally searches for pathogens in the body and helps the immune system fight against the infection. Following vaccination, the GLAASTM-activated dendritic cells recognize NY-ESO-1 as a foreign protein and cause the body to produce an <u>immune response</u>. Since NY-ESO-1 is found on tumors, the <u>immune system</u> begins targeting the cancer cells.

"Only 10 to 15 percent of all tumors have NY-ESO-1 protein expression.



Therefore, patients for this trial need to be to be screened for NY-ESO-1. The vaccine will likely not work for patients with tumors that do not have detectable levels of the protein," said Mahipal.

Each component of ID-G305 has been used previously as a single-agent in <u>clinical trials</u> and was well tolerated by patients. This trial will determine the ideal concentration of each agent to use in combination. Common side effects expected include pain, redness, and inflammation at the site of injection.

This is an exciting time for the development of new immunotherapies to fight cancer. Several immunotherapy agents have recently been approved by the Food and Drug Administration, including interleukin-2 for melanoma and <u>renal cell carcinoma</u>, Provenge for prostate cancer and ipilimumab for melanoma.

"New immune therapies are emerging," explained Mahipal. "If we can have <u>immune therapy</u> actually work it would be great for the patient and reduce side effects associated with traditional chemotherapies."

## Provided by H. Lee Moffitt Cancer Center & Research Institute

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