

## NCCS conducts world's first-in-human clinical trial of a novel vaccine targeting top cancers

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The National Cancer Centre Singapore (NCCS) has launched a clinical trial of a new cancer vaccine administered to human patients for the first time in the world. Cancer immunotherapy (the harnessing of the body's defence system to fight the patient's cancer, has emerged as one of the most exciting medical breakthroughs in the past two years.

In fact, the prestigious *Science* journal voted Cancer Immunotherapy the Breakthrough of the Year for 2013. Cancer Immunotherapy includes cancer vaccines, a form of treatment aimed at stimulating the body's immune cells to attack a target protein on cancer cells. This particular cancer vaccine encodes one of the most common proteins, MUC-1 that is expressed on many cancers, including ovarian, breast, prostate, colon, pancreas and lung cancer, but not expressed on normal cells.

The Singapore Clinical Research Institute (SCRI), a wholly-owned subsidiary of MOH Holdings, sponsored this clinical trial providing support that included project oversight, study drug importation, quality assurance and providing the medical expertise required in conducting a cancer trial.

Dr Toh Han Chong, NCCS Principal Investigator of the phase I clinical trial, who is also a Senior Consultant in the Division of Medical Oncology, said, "What makes this vaccine unique is that MUC-1 is attached to a protein that is intentionally designed to further enhance and



boost the efficiency and power of the body's immune system." This protein is called CD40-ligand (CD40L), to form a construct called MUC-1+CD40L.

This construct fits into the backbone of a hardy virus called adenovirus, which further improves the body's immune system specifically against MUC-1 expressed on the surface of the cancer, as demonstrated in convincingly superior animal study results. This vaccine has been developed by a United States biotech company, MicroVAX, and is injected under the patient's skin. The Singapore Clinical Research Institute (SCRI) is the sponsor for this clinical study.

So far, four <u>patients</u> have been treated with this cancer vaccine, the first time ever that human patients have been given this novel treatment. Of the four patients, two are diagnosed breast cancer and the remaining two have ovarian cancer. All four patients have tolerated this vaccine well, with no significant side effects. One patient with <u>advanced breast cancer</u> with cancer spread to her skin developed a skin rash about 2 weeks after treatment which disappeared a few days later.

"This skin rash may represent an immune reaction of the vaccine against her <u>breast cancer cells</u> which may be a good thing", explained Dr Toh. CEO of MicroVAX, Mr Jake Frank commented on this first-in-human study, "MicroVAX wishes to express its gratitude to the patients and their families who are participating in the testing of its TAA/ecdCD40L cancer vaccine in the phase I clinical trial currently being carried out under the direction of Dr Toh and his world class team at the National Cancer Centre Singapore with the support of the Singapore Clinical Research Institute.

"In preclinical studies, MicroVAX's TAA/ecdCD40L vaccine was found to induce a potent immune response that surpassed that induced by other immunological strategies. The TAA/ecdCD40L is unique as it can target



and destroy pre-existing cancerous tumours as well as prevent the development of cancer. In view of these unique features of the TAA/ecdCD40L vaccine platform, MicroVAX has been committed to bringing this vaccine technology to the clinic, and wishes to recognise the pivotal contributions of the SCRI and the NCCS in making this clinical trial possible."

Dr Teoh Yee Leong, Chief Executive Officer, SCRI said, "This trial showcases the strong tripartite partnership between an Academic Research Organisation like SCRI with a biotech company like MicroVAX and a prestigious healthcare institution like NCCS in conducting <u>clinical trials</u> in Singapore. It is also the first time SCRI is sponsoring a clinical trial to support the clinical trial community in Singapore and importantly patients participating in these trials are the ones to most benefit."

One of the cancer patients who received this <u>cancer vaccine</u> is 52-year-old Jane (her anglicised name) who lives in Helsinki, Finland. Jane has stage 4 ovarian <u>cancer</u>. Her husband had found this phase I clinical trial open for patient recruitment on the US National Institute of Health clinical trials website. Jane, who has been flying into Singapore every fortnightly since October last year, remains well and stable with no side effects from the vaccine whatsoever.

Another patient who participated in this trial is 60-year old Mrs Janet Quah who has stage 4 <u>breast cancer</u>. Both patients are happy to be interviewed for this media release.

## Provided by The National Cancer Centre Singapore

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