

Press Release

NCCS CONDUCTS WORLD'S FIRST-IN-HUMAN CLINICAL TRIAL OF A NOVEL CANCER VACCINE TARGETING TOP CANCERS IN SINGAPORE

- **A form of Cancer Immunotherapy, the cancer vaccine can enhance and boost the body's immune cells to attack a target protein in cancer cells**
- **Vaccine targets top cancers in Singapore such as colorectal, lung, prostate and breast cancer**
- **First-in-human clinical trial using adenovirus to receive endorsement from both U.S. Food and Drug Administration (FDA) and Health Sciences Authority (HSA)**
- **Clinical trial attracted an overseas patient, who travels from Helsinki to Singapore to participate in the trial**

Singapore, 21 January 2015 - 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 Deputy Director at NCCS and 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.

So far, four patients 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 advanced breast cancer 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 breast cancer cells 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 clinical trials 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 cancer vaccine is 52-year-old Jane (her anglicised name) who lives in Helsinki, Finland. Jane has stage 4 ovarian cancer. 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 breast cancer. Both patients are happy to be interviewed for this media release.

NCCS plans to recruit over 20 patients for this Phase 1 clinical trial over the next 12 months. For enquiries to participate in the trial, public can contact NCCS clinical research coordinator Ms Chong Hui Shan at +65 6436-8431 or chong.hui.shan@nccs.com.sg. General information about clinical trials is also available online at www.nccs.com.sg/.

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About National Cancer Centre Singapore

National Cancer Centre Singapore (NCCS) provides a holistic and multidisciplinary approach to cancer treatment and patient care. We treat almost 70 per cent of the public sector oncology cases, and they are benefiting from the sub-specialization of our clinical oncologists. NCCS is accredited by the US-based Joint Commission International for its quality patient care and safety. To deliver among the best in cancer treatment and care, our clinicians work closely with our scientists who conduct robust cutting-edge clinical and translational research programmes which have been internationally recognised. NCCS strives to be a global leading cancer centre, and shares its expertise and knowledge by offering training to local and overseas medical professionals. www.nccs.com.sg

About the Singapore Clinical Research Institute (SCRI)

Singapore Clinical Research Institute (SCRI) is a National Academic Research Organisation dedicated to enhance the standards of human clinical research. Its mission is to spearhead and develop core capabilities, infrastructure and scientific leadership for clinical research in Singapore. SCRI is a national clinical trials coordination centre that works with National Medical Research Council (NMRC) to assist the Ministry of Health in implementing clinical trials policy and strategic initiatives to support and develop clinical research competencies locally.

In driving towards its vision, SCRI collaborates with clinicians to enhance Singapore's clinical research and strengthen its expertise in executing multi-site, multi-national studies and the development of regional clinical research networks.

SCRI is a wholly-owned subsidiary of MOH Holdings. <http://www.scri.edu.sg>

About MicroVAX LLC

MicroVAX is a clinical stage biotech company located in Manassas, Prince William County, VA, dedicated to the development of potent vaccines, for treatment and preventive purposes, having application to the areas of cancer and infectious diseases for which effective solutions have not yet been developed. "As a member of the growing life sciences community in Prince William County and as a part of the George Mason University Enterprise Centre, MicroVAX is ideally situated in the heart of a well established research ecosystem with close proximity to key federal institutions, which have been and will continue to be instrumental as our R&D leads towards future FDA regulated clinical trials," said Jake Frank managing member of MicroVAX.3