Singapore to conduct Phase 2 Clinical Trial of Abbott’s Drug Candidate following successful “First-in-human” Phase 1 Study

A Singapore team of physician scientists from several hospitals has successfully completed the Phase 1 trial of a “small molecule” drug for treating advanced stages of lung cancer and other forms of cancer. The drug candidate was developed by Abbott, a global diversified healthcare company, which has several promising early stage oncology compounds. The results show very promising anti-cancer activity as a single drug in patients whose cancer has progressed while on other therapies.

With the success of Phase 1, Abbott has selected Singapore as one of the locations for the Phase 2 clinical trials of the same drug candidate. The clinical trials will commence in Singapore by the end of the year. The early phase trial was led by clinician-scientist Dr Goh Boon Cher of The Cancer Institute@National University Hospital, National Healthcare Group and the Yong Loo Lin School of Medicine, National University of Singapore.

The study was the first time that a “first-in-human” early cancer clinical trial by a major international healthcare company was conducted in Singapore. The traditional centres for clinical trials are located in the United States and Europe.

The study was conducted in NUH Clinical Trial Unit (CTU), a dedicated Phase I facility, which was started in 1997. NUH CTU has since conducted close to 100 trials, several of which were international multi-centered trials. With the support of an A*STAR programme known as the Singapore Cancer Syndicate and NUH’s strong track records in clinical studies of novel anti-cancer compounds, Dr Goh led a multi-disciplinary team of clinical oncology researchers, research coordinators, pharmacists, radiologists, physicists and computational scientists from several institutions to conduct this highly sophisticated study.

The study involved 21 advanced stage cancer patients who had exhausted all other forms of conventional treatments and who had agreed to participate in the trial. The new drug candidate is a small molecule that targets a class of enzymes
called tyrosine kinases that are often overly activated in cancer. The investigational compound, a VEGFR-based multi-targeted kinase inhibitor, suppresses tumor growth by preventing the growth of new blood vessels that supply the tumor with oxygen and nutrients and by inhibiting key angiogenic signaling pathways.

According to Dr Goh, the drug candidate showed promising clinical activity and manageable side effects in the Phase I trial. In particular, shrinkage of lung cancer was observed in some patients, and a specialized MRI scan that measured tumour blood flow showed reduction in blood flow in patients treated with the drug. The side effects observed were similar to other agents in the same class. Findings were presented at the Annual Meeting of the American Society of Clinical Oncology in June 2007.

‘First-in-human’ studies require a high level of medical and clinical research sophistication because of the complicated monitoring and assessment processes. The successful execution of this trial was seen by many as an indication of the maturity of the Singaporean early trials capabilities.

Prof Edison Liu, Executive Director of the Singapore Cancer Syndicate, said, “We are very pleased that Abbott has chosen Singapore as the location for the Phase I and expanded Phase 2 clinical trials of this new drug. With the rapid pace of drug development, the need to quickly, but carefully move new drugs and discoveries from the laboratory to the patient has never been more compelling. Abbott’s decision is clearly a strong sign that Singapore has the right infrastructure and people in place to establish ourselves as a centre for companies to conduct early-stage clinical trials of drug candidates. More importantly is that we are all pleased that Singapore may contribute to the development of a significantly efficacious anti-cancer agent. All patients will benefit.”

"Abbott’s experience partnering with The Cancer Institute and A*STAR was outstanding," said John Leonard, MD, Vice President, Global Pharmaceutical Research and Development, Abbott. “The team conducted high-quality science that provided us with important data about the safety and efficacy of our unique approach to suppressing angiogenesis in cancer patients who have failed other therapies. We look forward to working with them on our Phase 2 trial."

Besides having the right infrastructure in place, Singapore has a multi-ethnic population that is a pull factor for pharmaceutical companies to conduct early phase clinical studies in the city-state. While Phase 1 studies concentrate on studying drug effects, safety, tolerability and concentrations, Phase 2 will, in addition, concentrate on studying the antitumour effects of the drug in specific cancers. Doing these studies in Singapore gives an added dimension of studying drugs in different Asian ethnic groups by leveraging on the multi-ethnic population in Singapore.
After Phase I and Phase 2 clinical trials, therapies that are promising usually are subjected to large a randomised Phase 3 study, which would determine whether the drug should be added to standard practice. The whole process typically takes about 10 years.

“It is well-recognised that ethnic stratification is necessary for studying drug pharmacokinetics and pharmcodynamics, and with the emergence of Asia as a major pharmaceutical market, it is inevitable that drugs will have to be evaluated in an Asian context,” said Dr Goh Boon Cher, one of 11 distinguished clinician scientists in the National Healthcare Group (NHG). At any one time, more than 50% of about NHG’s 1400 doctors are involved in ongoing research projects, and there are more than 200 ongoing clinical trials at NHG institutions.

In March 2007, NHG became the first public healthcare institution outside North America to receive full accreditation from the Association for the Accreditation of Human Research Protection Programs Inc (AAHRPP).

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**About Abbott**

Abbott is a global, broad-based healthcare company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs 65,000 people and markets its products in more than 130 countries.

Abbott’s news releases and other information are available at the company’s website at [www.abbott.com](http://www.abbott.com).

**About Agency for Science, Technology and Research (A*STAR)**

[www.a-star.edu.sg](http://www.a-star.edu.sg)

The Agency for Science, Technology and Research, or A*STAR, is Singapore's lead agency for fostering world-class scientific research and talent for a vibrant knowledge-based Singapore.

A*STAR actively nurtures public sector research and development in Biomedical Sciences, Physical Sciences and Engineering, with a particular focus on fields essential to Singapore's manufacturing industry and new growth industries. It oversees 14 research institutes and supports extramural research with the universities, hospital research centres and other local and international partners.

At the heart of this knowledge intensive work is human capital. Top local and international scientific talent drive knowledge creation at A*STAR research institutes. The Agency also sends scholars for undergraduate, graduate and post-doctoral training in the best universities, a reflection of the high priority A*STAR places on nurturing the next generation of scientific talent.

**About SCS**

The Singapore Cancer Syndicate was established in 2002 under the auspices of the Agency for Science, Technology and Research (A*STAR) to enhance the translational of basic concepts in cancer biology and genetics to the clinic. The Cancer syndicate is mandated to fund critical clinical and translational infrastructure, support consortia around specific questions, and develop capabilities in areas of deficit. In this process, we now have established national pipelines for
translational investigation that span preclinical studies to pharmacokinetics, molecular pathology, genomic biomarkers, tumour registries to early phase clinical trial units.

The Mission of the Singapore Cancer Syndicate is to establish a robust and competitive translational platform for cancer research at a National level, with the ultimate aim of improving healthcare and treatment therapies of cancer patients in Singapore

**About the National Healthcare Group**

The National Healthcare Group (NHG) manages:

Four hospitals – Alexandra Hospital, National University Hospital, Tan Tock Seng Hospital and the Institute of Mental Health / Woodbridge Hospital;

The Johns Hopkins Singapore International Medical Centre; National Skin Centre;

The NHGP chain of nine polyclinics – Ang Mo Kio, Bukit Batok, Choa Chu Kang, Clementi, Hougang, Jurong, Toa Payoh, Woodlands, Yishun;

Three Specialty Institutes – The Cancer Institute, The Eye Institute and The Heart Institute; and

Six Business Divisions – NHG College, NHG Diagnostics, NHG Pharmacy, Jurong Medical Centre, Care Management Centres, and Singapore Footcare Centre.

Our vision is "Adding years of healthy life”.

**About the National University Hospital**

The National University Hospital (NUH), a member of the National Healthcare Group, is a specialist hospital that provides advanced, leading-edge medical care. Our unique position as university hospital enables us to be at the forefront of clinical research, and to translate new knowledge into safe, advanced treatment options for our patients.

With state-of-the-art facilities and dedicated, well-trained staff, NUH is a major referral centre for specialist care including Cardiology, Gastroenterology & Hepatology, Obstetrics & Gynaecology, Oncology, Ophthalmology, Paediatrics and Orthopaedic Surgery.

In 2004, NUH became the first hospital in Singapore to be accredited by the Joint Commission International (JCI), which is an international stamp for excellent clinical practices. It was also the first hospital to receive a triple ISO certification simultaneously for its Quality, Environmental, and Occupational Health & Safety Management Systems in 2002.

**About The Cancer Institute**

The Cancer Institute (TCI) of the National Healthcare Group (NHG) integrates the various cancer-related specialties at NHG, to provide comprehensive cancer services and programmes to tackle cancer. Its broad spectrum of cancer care ranges from public education, screening and early diagnosis, to treatment and long-term health maintenance. By utilising advanced therapies and facilities, drawing on the expertise of cancer specialists from different disciplines, patients are able to benefit from TCI’s high quality of inpatient and outpatient healthcare.
TCI adopts an evidence-based and team approach comprising of cancer specialists from the fields of medical oncology, haematology, radiation oncology, paediatric haematology/oncology, gynecologic oncology, surgical oncology, radiology, pharmacy, laboratory medicine and pathology, nursing oncology, and other allied health sciences.

TCI@NUH is actively engaged in cancer research and experimental cancer therapeutics with the aim of providing better customized therapies for individual patients. Besides initiating their own research studies, TCI's doctors collaborate with international research groups and partners in the pharmaceutical industries to conduct clinical trials on new and promising treatments for cancer.

Currently, The Cancer Institute's services are available at National University Hospital, Tan Tock Seng Hospital, Alexandra Hospital and NHG Polyclinics. We also collaborate with the general practitioners, clinical trial groups, hospices and cancer support groups to ensure that our patients receive the full continuum of care.