

Media Release

Interim analysis found SGH-led SIRveNIB regional phase III clinical trial to treat patients with locally advanced liver cancer right on track

2 July 2013 - Singapore General Hospital (SGH) today announced that an interim analysis by an Independent Data Safety Monitoring Committee has found that the SIRveNIB regional phase III investigator-initiated trial to be on track and has met its primary safety end points.

The primary responsibility of the Committee is to ensure the validity and integrity of the trial by performing on-going safety monitoring, as well as interim analysis for efficacy. For the SIRveNIB trial, the Committee has found it to be safe and recommends the trial to be completed without any changes to the trial protocol.

“We are delighted with the progress of this trial. This is an important trial to look at different treatment options for primary liver cancer. We hope the outcome of the trial, when available will be able to provide good information to the doctors in the region in treating this disease”, said Professor Pierce Chow, Senior Consultant, Department of General Surgery, SGH and Protocol Chair (Principal Investigator) of the trial.

The trial seeks to assess the effectiveness of two widely-used treatments (Sorafenib and SIR-Spheres) for locally advanced hepatocellular carcinoma (HCC) or liver cancer that has not spread outside of the liver. The aim is to determine which of these two therapies is more effective in the treatment of the disease. To date, about 200 patients have been recruited for the 360-patient clinical trial that is expected to complete in 2015.

Launched in July 2010, the trial is initiated under the Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC) and involves 28 centres in 11 countries including Korea, Hong Kong, New Zealand and Malaysia. It is jointly funded by the National Medical Research Council, Singapore and Sirtex with operational support by Singapore Clinical Research Institute (SCRI).

“This trial has shown that Singapore is able to coordinate large scale investigator-initiated clinical trials in the Asia Pacific region through good collaborations with the clinicians in the other countries,” said Dr Teoh Yee Leong, Chief Executive Officer, SCRI.

HCC is the 5th most common cancer worldwide. Almost 80 per cent of HCC cases are found in the Asia-Pacific region. As the majority of patients with liver cancer do not develop any symptoms, only one in five of them can potentially be cured by surgery when diagnosed.

PATIENTS. AT THE HE^{ART} OF ALL WE DO.[®]

Members of the SingHealth Group

Singapore General Hospital - KK Women's and Children's Hospital
National Cancer Centre Singapore - National Dental Centre Singapore - National Heart Centre Singapore
National Neuroscience Institute - Singapore National Eye Centre - SingHealth Polyclinics - Bright Vision Hospital

About SIRveNIB Trial

Eligible patients who are enrolled in the trial will either undergo oral therapy, taking two tablets of Sorafenib twice a day for as long as the drug continues to be efficacious and the patient has minimal side-effects; or a single administration of SIRT (Yttrium-90) through a microcatheter directly into the liver.

Patients must meet the following inclusion criteria to be enrolled into the study:

- Must be at least 21 years of age
- Must be willing to comply with study-related procedures and tests
- Must have locally advanced liver cancer (i.e. the cancer has not spread to other organs)
- Must have locally advanced liver cancer that cannot be treated by surgery or other curative therapies
- Must be independent and able to perform daily living activities
- Must have adequate bone marrow, liver and renal function
- Must not have received any systemic chemotherapy for the past 6 months
- Must not have had more than two administrations of hepatic artery – directed therapy, or received hepatic artery – directed therapy less than 4 weeks prior to study entry
- Must not have received prior hepatic radiation therapy for HCC or other malignancy

About Singapore General Hospital

Singapore General Hospital, a member of Singapore Health Services, is the public sector's flagship hospital. Established in 1821, SGH is Singapore's largest acute tertiary hospital with 1,700 beds and national referral centre offering a comprehensive range of 36 clinical specialties on its campus. Every year, about 1 million Singaporeans benefit from advanced medical care delivered by its 800 specialists. As an academic healthcare institution and the bedrock of medical education, SGH plays a key role in nurturing doctors, nurses and allied health professionals, and is committed to innovative translational and clinical research in her continual strive to provide the best care and outcomes to her patients.

About Asia-Pacific Hepatocellular Carcinoma (AHCC) Trials Group

The Asia-Pacific Hepatocellular Carcinoma (AHCC) Trials Group is a collaborative group formed in 1997 by clinicians treating hepatocellular carcinoma in major medical centres in the Asia-Pacific region. The aims of the trials group are to conduct preventive and therapeutic trials in hepatocellular carcinoma, to carry out basic and translational research in this field and to develop training and educational programs pertaining to HCC.

PATIENTS. AT THE HEART OF ALL WE DO.

Members of the SingHealth Group

Singapore General Hospital - KK Women's and Children's Hospital
National Cancer Centre Singapore - National Dental Centre Singapore - National Heart Centre Singapore
National Neuroscience Institute - Singapore National Eye Centre - SingHealth Polyclinics - Bright Vision Hospital

About Singapore Clinical Research Institute

The Singapore Clinical Research Institute (SCRI) is an organization with the strategic imperative to enhance the standards of human clinical research through driving the development of core capabilities, infrastructure, intellectual and scientific leadership in Singapore. Its vision is to develop SCRI and Singapore scientists as an ASEAN hub for clinical research excellence.

The SCRI houses an experienced and highly-qualified team of scientists and research staff, offering a comprehensive suite of clinical research capabilities. These areas of expertise range from clinical project development and execution, including protocol/study design, project management and, site monitoring, data management/biostatistical analysis, epidemiology and evidence synthesis and training on various aspects of clinical research. In driving towards its vision, SCRI continues to enhance Singapore's clinical research capabilities and strengthen its expertise in executing single and multisite, multinational research and the development of regional clinical research networks.

For media enquiries, please contact:

Ms Carol Ang

Assistant Manager, Communications

DID: 6321 4999 / Mobile: 9845 5354

Email: Carol.Ang@sgh.com.sg

Ms Junaidah Hameed

Senior Manager, Communications

Singapore General Hospital

Tel: 6321 3553 / 8125 1707

Email: Junaida.Hameed@sgh.com.sg

PATIENTS. AT THE HEART OF ALL WE DO.

Members of the SingHealth Group

Singapore General Hospital - KK Women's and Children's Hospital

National Cancer Centre Singapore - National Dental Centre Singapore - National Heart Centre Singapore

National Neuroscience Institute - Singapore National Eye Centre - SingHealth Polyclinics - Bright Vision Hospital