



MEDIA RELEASE

LIVER CANCER CLINICAL TRIAL SUCCESSFULLY ENTERS 2ND PHASE

- **Trial involves combining two liver cancer treatment modalities**
- **Phase I, which tests early safety and toxicity of the new treatment has been completed**

Singapore, 23 December 2008 – The horizon may possibly be brighter for inoperable hepatocellular carcinoma (HCC), or primary liver cancer sufferers, going by the successful conclusion of the first phase of a landmark clinical trial currently carried out by the Asia-Pacific Hepatocellular Carcinoma (AHCC) Trials Group.

The second phase of the trial has commenced and is expected to complete recruitment by 2009.

The AHCC Trials Group, which has its secretariat at the National Cancer Centre Singapore (NCCS), aims to pioneer new treatment modalities for liver cancer patients, especially those with advanced disease which generally has a median survival of less than three months. Liver cancer is especially prevalent in Asia and the trials group consists of various member medical centres from countries around the region, including Singapore.

The current clinical trial began in Singapore in June 2008, and is unique in that it combines two established treatment modalities, namely, an oral-targeted chemotherapy drug called Sorafenib, and SIR-Spheres, an internal radiation therapy applied through a catheter. The current standard practice uses either one to treat liver cancer.

NCCS Director Prof Soo Khee Chee, who is also the Group Chair of the AHCC Trials Group, said that the completion of the first phase is crucial as it assesses the early safety of this new treatment approach.

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He said: “As medical professionals, we need to be absolutely certain that our treatments are highly effective and at the same time not have unacceptably high risks of major side-effects. With the conclusion of the phase I of this trial, we are satisfied with its safety profile.”

Associate Prof Pierce Chow, who is the Protocol Chair of the clinical trial, highlighted the significance of completing the first phase of the trial:

“One of the biggest hurdles in adopting new treatments undoubtedly concerns unexpected safety issues. While associated side effects are a possibility with all therapies, these rates must not be unacceptably high or hazardous. It is not unusual for trials to fail at this stage as new developments in medical treatment are extremely complex and contain an element of unpredictability. Thus we are pleased with the satisfactory closure of phase I of the trial. We have proceeded with phase II of this trial of a novel therapeutic combination that potentially prolongs the lives of inoperable liver cancer patients.

“In phase I of the trial, no unacceptably high rates of side effects of the treatment was encountered and the majority of the patients have done well. Phase II will assess the efficacy of the combined treatment modality. We expect similar good results from our colleagues in Malaysia, South Korea when they come onboard the trial early next year.”

Nine local patients entered the first phase of the trial and were followed up for assessment of adverse events by a committee. Currently a total of 23 local patients (20 males and three females, ages between 55 and 70) have been enrolled in the trial. Centres from Korea and Malaysia are expected to enter patients by early 2009 as both centres have received approval from their respective Institutional Review Boards. Other centres such as those from Myanmar are expected to follow. The trial will close once 35 patients have been recruited. Both the Singapore General Hospital and the National Cancer Centre Singapore are participating in the trial.

During the trial, patients are first administered SIR-Sphere therapy and are subsequently prescribed Sorafenib, an oral targeted anti-cancer drug.

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A large clinical trial on patients with advanced HCC has shown that treating these patients with Sorafenib alone resulted in improvement in survival that translates to an extension in life-span of three months. This is the only cancer drug that has been scientifically proven to extend survival in patients with advanced HCC. However, while Sorafenib does not confer tumour regression (shrinkage), SIR-Sphere therapy has consistently been reported to result in significant tumour regression. It is thus hoped that this combination treatment will confer better outcomes for patients.

A/Prof Chow said: “Through this clinical trial, we hope that the combination of these two treatment modalities will extend a patient’s outcome beyond that which is provided by either one of these treatment modalities on their own. The trial will be considered successful if that objective is attained.”

The AHCC Trials Group was formed with support from the Singapore Millenium Foundation. The current clinical trial is the 5th clinical trial that the group is conducting and is supported by the National Medical Research Council (NMRC), pharmaceutical company Bayer Schering Pharma Singapore and Sirtex Medical Products, a bio-technology company. Sorafenib is manufactured by Bayer Schering Pharma Singapore, while SIR-Spheres are therapeutic medical devices from Sirtex Medical Products. Both companies are each contributing approximately S\$1.5 million in therapeutics, with the NMRC providing another S\$468,200.

About NCCS

The National Cancer Centre Singapore (NCCS) is the premier cancer research and treatment facility in Singapore and in the region. It was established in 1997 and sees over 60 percent of the public sector medical oncology cases and about 70 percent of radiation oncology cases. NCCS not only houses the most number of oncologists in Singapore but is also equipped with the largest number of equipment to provide the latest radiation oncology care in Singapore. For more information, visit NCCS website at www.nccs.com.sg.

About AHCC

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

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this field and to develop training and educational programs pertaining to HCC. For more information, visit AHCC website at <http://www.cteru.com.sg/ahcc/index.htm>.

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