

Liver Cancer Researchers from AP-HP and Singapore Collaborate on a Prospective Meta-Analysis of Two Studies of Y-90 resin microspheres versus Sorafenib in Patients with Unresectable Hepatocellular Carcinoma (HCC)

Paris, France and Singapore (6 October 2016) --

Cancer researchers from Assistance Publique – Hôpitaux de Paris (AP-HP) and The Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC), National Cancer Centre Singapore (NCCS) and Singapore Clinical Research Institute (SCRI) announced that they will collaborate on a prospective meta-analysis that will combine the impending results of two large, randomized controlled studies of Y-90 resin microspheres* versus sorafenib. The two studies, which have completed patient recruitment, enrolled approximately 800 patients with advanced primary liver cancer (hepatocellular carcinoma or HCC).

The French HCC study, called SARAH, sponsored by AP-HP with the financial support of the company Sirtex, and the Singapore HCC study, called SIRveNIB (AHCC protocol 06), which also received financial support from Sirtex, use similar research designs to compare the efficacy, safety profiles and quality of life (QoL) of selective internal radiation therapy (SIRT) with liver-directed Y-90 resin microspheres and sorafenib, a systemic chemotherapy treatment that is the current standard of care in advanced hepatocellular carcinoma. HCC patients enrolled in SARAH and SIRveNIB were ineligible for potentially curative therapies, such as surgical resection, ablation or liver transplantation and had either failed or were unsuitable for treatment with Trans-Arterial Chemo-Embolisation (TACE).

Professor Pierce Chow, Principal Investigator of the SIRveNIB study, and Senior Consultant Surgeon at the National Cancer Centre Singapore and the Singapore General Hospital, explained that, “As we stated when we first announced completion of enrolment in SIRveNIB, the search for more effective and better tolerated treatments of HCC is important because so few proven treatment options currently exist. Our study enrolled more than 360 patients from 27 specialist centres in 10 Asia-Pacific countries. While our data will be reported independently, the opportunity to combine these data in a prospective meta-analysis with the results of the French SARAH study presents a compelling scientific undertaking across a

much larger patient population that will significantly increase the data available for various pre-planned statistical analyses, including overall survival. This should provide physicians who treat HCC with even greater certainty of the applicability of our results in the treatment of this increasingly common and deadly cancer.”

Professor Valérie Vilgrain MD, PhD, Principal Investigator of the SARAH study, Head of Department of Radiology, Beaujon Hospital AP-HP, and Professor at the Université Paris Diderot, Sorbonne Paris Cité, France, said that “The SARAH study was conducted in more than 25 specialist centres throughout France and is expected to report results in the first half of 2017. While we will also report the results of SARAH independently, we believe a prospective meta-analysis of our findings combined with those of the SIRveNIB study may be very compelling. HCC in France and most of Europe is found in patients whose livers have become cirrhotic primarily from the Hepatitis C virus and alcohol misuse, while the majority of HCC cases in Asia are triggered initially by the Hepatitis B virus. Thus, our prospective meta-analysis will provide safety and efficacy data on patients who presented with a full range of the major HCC aetiologies, potentially increasing the clinical applicability of the study results.”

Results of the prospective meta-analysis are expected to be available in 2017. In the interim, further details regarding the methodological and statistical approach to the meta-analysis are to be published in a peer-reviewed journal.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of primary liver cancer – cancer that starts in the liver – which is the sixth most-common cancer in the world and the second most-common cause of cancer-related death. It affects mainly patients with cirrhosis from any cause, including viral hepatitis and alcohol abuse. HCC occurs with greatest frequency in regions where hepatitis is most often diagnosed, such as in the Asia Pacific region and Southern Europe. When diagnosed in its early stages, HCC can be treated by surgical resection, ablation or liver transplantation with expectation of improved long-term survival. However, these options are not available to the great majority of patients. For patients with unresectable HCC, the outlook is bleak, with survival ranging from a few months to about two years depending largely on the extent of their tumours and state of their liver at the time of diagnosis. No new HCC treatment option has been tested successfully in large studies for almost a decade.

About AP-HP, Greater Paris University Hospitals

Beaujon Hospital, the principle centre of the SARAH study is part of the Public Hospital System of the City of Paris, AP-HP. The AP-HP is affiliated with a university and has a European dimension that is recognised worldwide. Its 39 hospitals admit 8 million sick persons every year for consultation, emergency treatment, for scheduled hospitalization or hospital at home. It assures public health service for everyone, 24/7; this is its pride and purpose. The AP-HP is the largest employer of the Ile de-France: 95,000 people – physicians, researchers, paramedics, administrative personnel and workers – are employed there. Its teams also pursue an important clinical research activities. In 2015 its teams conducted more than 3,400 research projects, and published more than 9100 scientific publications, accounting for 40% of all French medical research publications. The AP-HP holds a portfolio of 825 active international patents. For more information, visit the AP-HP website at www.aphp.fr/international

About Asia-Pacific Hepatocellular Carcinoma 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. For more information, visit the AHCC website at

www.scri.edu.sg/crn/asia-pacific-hepatocellular-carcinoma-ahcc-trials-group/about-ahcc/

About National Cancer Centre Singapore

National Cancer Centre Singapore (NCCS) provides a holistic and multi-disciplinary 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-specialisation of our clinical oncologists. NCCS is also 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 programs which are 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. For more information, visit the NCCS website at www.nccs.com.sg

About Singapore Clinical Research Institute

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. For more information, visit the SCRI website at www.scri.edu.sg

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* SIR-Spheres® Y-90 resin microspheres are indicated for the treatment of non-resectable metastatic liver tumours from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine.

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