SIR*ve*NIB, a Major Primary Liver Cancer Study in the Asia-Pacific Region, Completes Enrolment

Results of Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC) Randomised Controlled Study Comparing Sorafenib and SIR-Spheres® Y-90 resin microspheres in the Treatment of Unresectable Hepatocellular Carcinoma (HCC) Expected in 2017

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The Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC), National Cancer Centre Singapore, Singapore Clinical Research Institute (SCRI) and Sirtex Medical Limited announced that the AHCC protocol 06 SIR*ve*NIB randomised controlled study of SIR-Spheres Y-90 resin microspheres versus sorafenib in the treatment of unresectable primary liver cancer (hepatocellular carcinoma or HCC) has completed its target enrolment of at least 360 patients.[1]

SIR*ve*NIB was designed to compare the efficacy and safety of selective internal radiation therapy (SIRT) with yttrium-90 [Y-90] resin microspheres (SIR-Spheres®, Sirtex Medical Limited, North Sydney, Australia) versus sorafenib (Nexavar®, Bayer HealthCare Pharmaceuticals, Berlin, Germany), a systemic treatment that is the current standard of care in advanced hepatocellular carcinoma. The patients in SIR*ve*NIB were ineligible for potentially curative therapies, such as surgical resection, ablation or liver transplantation.

Professor Pierce Chow, Principal Investigator of the SIR*ve*NIB study, and Senior Consultant Surgeon at the National Cancer Centre Singapore and the Singapore General Hospital, explained that, “The search for more effective and better tolerated treatments of HCC is important, as so few proven treatment options currently exist. Beyond the primary endpoint of overall survival in SIR*ve*NIB, we are also looking at a number of important secondary endpoints including a comparison of the side effects and patient quality of life with these two very different approaches to treating unresectable HCC. SIR*ve*NIB is the largest Asia-Pacific study to directly compare SIRT and sorafenib, and indeed is the largest randomised study conducted on sorafenib in the region.”

“Completion of patient enrolment in the investigator-led SIR*ve*NIB study represents a milestone in Asian liver cancer research, and underscores the strong private-public partnership that exists between Sirtex Medical Limited, the National Cancer Centre Singapore and Singapore Clinical Research Institute”, said Associate Professor Teoh Yee Leong, CEO Singapore Clinical Research Institute.

SIR*ve*NIB patients were treated at 27 centres across 10 Asia-Pacific countries including New Zealand. The results of SIR*ve*NIB are expected to become available in the first half of 2017.

Sorafenib was established as the standard treatment for patients with advanced HCC following the results of two pivotal randomized controlled trials which demonstrated an increased overall survival compared to placebo.[2,3] However, 80% of patients receiving sorafenib also experienced treatment-related adverse events. SIRT with SIR-Spheres Y-90 resin microspheres is an approved treatment for inoperable liver tumours. It is a minimally-invasive treatment that delivers high-energy beta radiation directly to the tumours. SIRT is administered to patients by interventional radiologists, who infuse

millions of radioactive microspheres (whose diameters are around 32.5 microns, or about one-third the diameter of a human hair) via a catheter into the liver arteries that supply blood to the tumours. The microspheres use the tumours' own blood supply to deliver a dose of short-range radiation that is up to 40 times higher than conventional radiotherapy, while sparing healthy tissue. Interest in a randomized controlled study of SIRT using Y-90 resin microspheres in this patient population was based on a substantial number of open-label single-centre studies as well as a large multi-centre analysis of the long-term outcomes following SIR-Spheres Y-90 resin microspheres in patients with inoperable HCC.[4]

Current Availability of SIR-Spheres Y-90 resin microspheres

SIR-Spheres Y-90 resin microspheres are approved for the treatment of inoperable liver tumours in Australia, the European Union (CE Mark), Argentina (ANMAT), Brazil, and several countries in Asia, such as Turkey, India and Singapore. The product is also supplied for this use in countries such as Hong Kong, Israel, Malaysia, New Zealand, Taiwan and Thailand. SIR-Spheres Y-90 resin microspheres also have a full Pre-Market Approval (PMA) by the FDA and are indicated in the United States for the treatment of non-resectable metastatic liver tumours from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine.

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.[5] 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.[6] No new HCC treatment option has been tested successfully in large studies for almost a decade.

About the SIR*ve*NIB Study Sponsors

SIR*ve*NIB is an investigator-initiated study sponsored by Singapore General Hospital in collaboration with National Medical Research Council, Singapore, National Cancer Centre Singapore, and the Singapore Clinical Research Institute and Sirtex Medical Limited.

For further information, please visit:

Singapore General Hospital	www.sgh.com.sg
National Medical Research Council, Singapore	www.nmrc.gov.sg
National Cancer Centre Singapore	www.nccs.com.sg
Singapore Clinical Research Institute	www.scri.edu.sg
Sirtex Medical Limited	www.sirtex.com

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