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# Sirtex invests in major new Asia Pacific study to expand clinical use

Oncology treatment company Sirtex Medical Limited (ASX: SRX) today announced a major new clinical study to directly compare the effectiveness of its targeted radioactive SIR-Spheres® microspheres for inoperable primary liver cancer against the current standard of care chemotherapy drug sorafenib (Nexavar®, Bayer HealthCare Pharmaceuticals, Germany)

The Phase III prospective randomised controlled trial, called SIR*ve*NIB, will this month start recruiting up to 360 patients at 25 to 30 sites across the Asia Pacific region, including Australia.

The primary goal of the study will be to assess if SIR-Spheres microspheres gives patients an increased survival benefit compared to sorafenib when used to treat patients with intermediate and advanced primary liver cancer, also known as hepatocellular carcinoma (HCC).

About 80 per cent of patients who contract HCC are not suitable for surgery or transplantation. SIR-Spheres microspheres are currently used to extend the lives of patients with liver cancer after chemotherapy options have been exhausted.

The SIR*ve*NIB study, headed by Professor Pierce Chow, Senior Consultant Surgeon, Singapore General Hospital and Visiting Senior Consultant, National Cancer Centre Singapore, is being conducted by the Asia Pacific Hepatocellular Carcinoma Trials Group (AHCC).

Professor Chow said, "While Nexavar is efficacious therapy for the treatment of patients with HCC for whom surgery is not an option, current data suggests SIR-Spheres microspheres may represent an alternative option with equal or better efficacy when there is no distant cancer spread. This multi-centre clinical trial by the AHCC trials group will establish this in a scientific manner".
Data presented by Professor Chow earlier this month at the American Society of Clinical Oncology (ASCO) Annual meeting in Chicago, supported the therapeutic benefit of the combination of SIR-Spheres microspheres and sorafenib in the treatment of intermediate and advanced HCC.[1] (refer Sirtex ASX announcement 8th June 2010)

"This next study will compare the safety and therapeutic benefit of the two agents to determine which of these two therapies should be first-line treatment for locally advanced HCC," Professor Chow said. The SIR*ve*NIB study is collaboration between Sirtex, the Asia Pacific Hepatocellular Carcinoma Trials Group (AHCC), the National Cancer Centre Singapore, and the National Medical Research Council in Singapore, the Singapore Clinical Research Institute and Singapore General Hospital.

Sirtex's Chief Executive Officer, Gilman Wong, said "Investment in this new study is part of our long term plan to significantly expand our business by realising the full potential of SIR-Spheres microspheres and is another key milestone in the evolution of the Company's global clinical program currently consisting of 12 clinical trials. The SIR*ve*NIB study is the fourth large scale randomised controlled trial supported by Sirtex as part of our commitment to further global clinical research for the betterment of the patients we serve."

"We expect that the results of the SIR*ve*NIB trial will establish SIR-Spheres microspheres as a new standard of care for patients who currently have limited treatment options available. We are delighted to be collaborating with the Asia Pacific Hepatocellular Carcinoma Trials Group, National Cancer Centre Singapore, National Medical Research Council Singapore, the Singapore Clinical Research Institute and Singapore General Hospital in order to benefit patients further," Mr Wong said.

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**Reference:**

1. Chow PKH *et al*. Multicentre Phase II study of SIR-Spheres plus sorafenib as first-line treatment in patients with nonresectable hepatocellular carcinoma: The Asia-Pacific Hepatocellular Carcinoma Trials Group Protocol 05 (AHCC05). *ASCO Annual Meeting,* Chicago, Illinois, 2–8 June 2010; *J Clin Oncol* 2010; 28 (Suppl 7S): Abs. 4072.