



Major Liver Cancer Study Completes Palliative Cohort Enrolment

Palliative Group of SORAMIC Study on Treatment of Locally Advanced Primary Liver Cancer with SIR-Spheres® Y-90 resin microspheres followed by Sorafenib Reaches 420-patient Enrolment Target

Magdeburg, Germany, 7 March 2016 --

Prof. Dr. Jens Ricke, Professor of Radiology at the University of Magdeburg, announced that the palliative cohort of the Pan-European SORAMIC¹ study he co-directs with Prof. Dr. Peter Malfertheiner has reached its enrolment target of 420 patients with unresectable primary liver cancer (hepatocellular carcinoma or HCC). HCC is the world's third leading cause of cancer deaths.

SORAMIC is the first large randomised controlled trial (RCT) to compare the efficacy and safety of combining standard systemic therapy with sorafenib (Nexavar®, Bayer, Germany) and liver-directed selective internal radiation therapy (SIRT) with Y-90 resin microspheres (SIR-Spheres®, Sirtex Medical Limited, Australia) versus sorafenib alone in the treatment of HCC in the palliative cohort. Patients with primary liver cancer who took part in the palliative cohort of the SORAMIC study were not eligible for resection or ablation, and were not suitable candidates for trans-arterial chemoembolization (TACE), an interventional technique for treating liver tumours locally, with chemotherapy-eluting beads. Results of the SORAMIC study are expected in 2018.

SORAMIC, which is an acronym for "Sorafenib and Micro-therapy Guided by Primovist®-Enhanced MRI in Patients with Inoperable Liver Cancer", is an Investigator-Initiated Trial (IIT). The study consists of two parts: the diagnostic part and the therapeutic part. In the diagnostic part of the study, contrast-enhanced magnetic resonance imaging (MRI) and computed tomography (CT) will be compared to determine if MRI is at least comparable to CT for identification of HCC lesions in guiding initial treatment decisions and patient management. Based on available results, there is reason to assume that Gd-EOB-DTPA (Primovist®, Bayer, Germany)-enhanced MRI is able to improve the accuracy of the detection of HCC lesions. If correct, this should improve the selection of appropriate treatment. In the therapeutic part, new combinations of therapeutic procedures compared to today's general practice. The palliative cohort is for patients with locally advanced HCC, i.e. metastases in bones or lymph nodes.

SORAMIC continues to recruit for another study cohort with curative intent (comprising of radiofrequency ablation [RFA] plus sorafenib vs. RFA plus placebo) and the diagnostic sub-study.

Prof. Dr. Ricke, who is director of the Clinic for Radiology and Nuclear Medicine at Magdeburg, said that “for the past ten years, sorafenib has been the sole standard of care for treating patients with advanced HCC, or any HCC that has spread beyond the liver. We hope that the results of this large RCT will demonstrate that the combination of sorafenib and Y-90 resin microspheres may provide a new treatment standard for patients with HCC who are not eligible for surgical resection or ablation.”

Sorafenib was established as the standard treatment for patients with advanced HCC following the results of the pivotal SHARP randomized controlled trial, which demonstrated an increased median overall survival from 7.9 to 10.7 months compared to placebo.²

The multi-disciplinary SORAMIC study was launched six years ago, in February 2010. An interim safety analysis based on data from the first 40 patients enrolled in the palliative study cohort indicated that treatment with Y-90 resin microspheres followed by escalated dosage of sorafenib was not associated with increased toxicity compared to sorafenib alone in patients with locally advanced HCC. Patients treated with the combined therapies benefited from the same intensity and duration of sorafenib treatment as the control patients who received sorafenib alone.³

Results are expected later this year for the SARAH RCT, which directly compares the efficacy and safety of sorafenib to that of Y-90 resin microspheres in patients with unresectable HCC who have failed TACE or are unable to receive it. SIRveNIB, a second RCT that has the same design as SARAH, is expected to also complete recruitment during 2016.

About Hepatocellular Carcinoma (HCC)

Hepatocellular Carcinoma (HCC) is the most common form of primary liver cancer – cancer that starts in the liver. HCC is the seventh most common cancer in the world and the third most common cause of cancer-related death.⁴ It affects mainly patients with cirrhosis from any cause, including viral hepatitis and alcoholism and occurs with greatest frequency in regions where hepatitis is most often diagnosed, such as in the Asia Pacific region and Southern Europe. HCC can be treated surgically by resection or transplantation with some chance of 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.⁵ No new option has been tested successfully in large studies for almost a decade.

About the sponsor, the Medical Faculty of the Otto von Guericke University, Magdeburg

The University Medical Center Magdeburg consists of the Medical Faculty of the Otto von Guericke University and the University Hospital Magdeburg as a public institution with more than 50 clinics, institutes and service facilities that engage in close interdisciplinary collaboration. The essence of the University Medical Center is the inseparable connection of research, teaching and academic training of physicians and the treatment of particularly serious illnesses.

The University Medical Center Magdeburg employs over 4,300 physicians, nursing staff, scientists, research associates and administrative staff. More than 1,500 future physicians are currently studying at the Medical Faculty.

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