3 February 2012

NEW STUDY OF PRIMARY LIVER CANCER SEEKS TO ENROLL 400 FRENCH PATIENTS

'SARAH' – a French national collaborative randomized controlled trial of radioembolization with yttrium-90 resin microspheres versus sorafenib in advanced hepatocellular carcinoma is now open for recruitment

The start of SARAH, a new randomized controlled trial to directly compare the effectiveness of radioembolization with yttrium-90 resin microspheres (SIR-Spheres® microspheres; Sirtex Medical Limited, Australia) versus sorafenib (Nexavar®, Bayer HealthCare Pharmaceuticals, Germany), a systemic therapy that is the current standard of care for patients with non-surgical advanced hepatocellular carcinoma (HCC), was announced today by the principal investigator, Professor Valérie Vilgrain MD, PhD, Department of Radiology, Beaujon Hospital, Assistance Publique – Hôpitaux de Paris, Clichy and Université Paris Diderot, Sorbonne Paris Cité, France.

SARAH (SorAfenib versus Radioembolization in Advanced Hepatocellular carcinoma) is a Phase III multi-centre prospective randomized open-labelled trial, which aims to recruit 400 patients in France with advanced HCC (Barcelona Clinic Liver Cancer stage C) with or without portal vein thrombosis and no extrahepatic spread, who are ineligible for surgical resection, liver transplantation or radiofrequency ablation; or whose disease has progressed or recurred after previous therapies.[1]

The primary goal of the study will be to assess if radioembolization with yttrium-90 resin microspheres provides an increased survival benefit compared to sorafenib in patients with advanced HCC.

Professor Vilgrain said: "Around 20 specialist cancer centres throughout France will be involved in this trial. SIR-Spheres microspheres were selected for the test arm of this collaborative trial, which is being promoted by the 'Assistance Publique – Hôpitaux de Paris'."

In patients with advanced HCC, sorafenib is now the standard treatment. Its use is associated with an increased median overall survival (from 8 to 11 months in the SHARP trial) but 80% of patients also experience treatment-related adverse events.

Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a novel treatment for inoperable liver cancer that delivers high doses of radiation directly to the site of tumours. It is a minimally-invasive treatment, in which millions of radioactive SIR-Spheres microspheres (diameter between 20-60 microns) are infused via a catheter into the liver, where they selectively target liver tumours with a dose of internal radiation up to 40 times higher than conventional radiotherapy, while sparing healthy tissue. There is a growing interest in radioembolization using yttrium-90 resin microspheres in this patient population, based on a substantial number of open-label single-group studies as well as a large multi-centre European analysis[2] of the long-term outcomes related to survival and safety of radioembolization using SIR-Spheres microspheres in patients with inoperable HCC. In 13 open-label single-group studies totalizing 400 patients with advanced HCC, the combined estimation of the median overall survival after radioembolization with yttrium-90 microspheres was of 15 months (min-max: 7 to 27 months).

SIR-Spheres microspheres are approved for use in Australia, the European Union (CE Mark), New Zealand, Switzerland, Turkey and several other countries including in Asia (e.g. India, Korean, Singapore and Hong Kong) for the treatment of unresectable liver tumours. SIR-Spheres microspheres are also indicated in the U.S. for the treatment of non-resectable metastatic liver tumours from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine.

Professor Vilgrain said that: "The SARAH trial is testing the hypothesis that radioembolization using yttrium-90 resin microspheres can increase the median overall survival with fewer side effects and/or a better quality of life in comparison with sorafenib. We hope that the results of this study will help improve the prognosis for these difficult to treat patients".

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) occurs in people whose livers have become severely damaged or cirrhotic, due to conditions such as hepatitis and alcoholism. It is one of the ten most-common cancers in the world, with nearly 750,000 cases diagnosed annually, and the third-leading cause of cancer deaths.[3] It occurs with greatest frequency in regions where viral hepatitis B or C are most often diagnosed, such as in Asia Pacific and Southern Europe.

Hepatocellular cancer can be cured by surgery, either by resecting the diseased parts of the liver, or by transplantation with a liver from a healthy donor. These interventions, however, are inappropriate for the great majority of patients, whose survival may range from a few months to two or more years depending largely on the state of their liver at the time of their diagnosis and the extent of tumour invasion**.**

References:

1. SorAfenib versus Radioembolization in Advanced Hepatocellular carcinoma (SARAH): http://clinicaltrials.gov/ct2/show/NCT01482442.

2. Sangro B, Carpanese L, Cianni R *et al* on behalf of European Network on Radioembolization with yttrium-90 resin microspheres (ENRY). Survival after ^{90}Y resin microsphere radioembolization of hepatocellular carcinoma across BCLC stages: A European evaluation. *Hepatology* 2011; **54**: 868–878.

3. GLOBOCAN. Liver Cancer Incidence and Mortality Worldwide in 2008. http://globocan.iarc.fr/factsheets/cancers/liver.asp accessed 28 June 2011.

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