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**TREATMENT OF PRIMARY LIVER CANCER:
SARAH STUDY NOW AVAILABLE FOR ALL ELIGIBLE PATIENTS
THROUGHOUT FRANCE**

Launched by the Assistance Publique - Hôpitaux de Paris (AP-HP) in December 2011, SARAH, a French national collaborative randomized controlled trial of radioembolization with yttrium-90 resin microspheres versus sorafenib in advanced hepatocellular carcinoma seeks to enroll 400 patients

To date, more than 150 patients have taken part in this study

In patients with advanced HCC, sorafenib (Nexavar[®], Bayer HealthCare Pharmaceuticals, Germany), with which radioembolization is being compared, 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. The SARAH trial is testing the hypothesis that radioembolization using yttrium-90 resin microspheres (SIR-Spheres[®] microspheres; Sirtex Medical Limited, Australia) can increase the median overall survival with fewer side effects and/or a better quality of life in comparison with sorafenib.

Coordinated at the national level by Professor Valérie Vilgrain MD, PhD (Department of Radiology, Beaujon Hospital, AP-HP) – Principal Investigator of this large study, 19 specialist cancer centres throughout France (Angers, Bondy, Bordeaux, Caen, Clichy, Créteil, Dijon, Grenoble, Marseille, Montpellier, Nancy, Nantes, Nice, Paris, Poitiers, Saint Etienne, Strasbourg, Villejuif; cf. <http://clinicaltrials.gov/ct2/show/NCT01482442>) are currently accruing patients. The aim is to recruit 400 patients in France with the following inclusion criteria:¹

- Patients with advanced HCC with or without portal vein thrombosis or whose disease has progressed after chemoembolization or recurrence of HCC;
- No extrahepatic spread;

- Ineligible for:
 - surgical resection;
 - liver transplantation;
 - radiofrequency ablation.

There is a growing medical 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 analysis² of the long-term outcomes related to survival and safety of radioembolization using SIR-Spheres microspheres in patients with inoperable HCC.

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 indicated in the U.S. for the treatment of unresectable metastatic liver tumors from primary colorectal cancer together with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).

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.

About Selective Internal Radiation Therapy (SIRT)

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.

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 ⁹⁰Y 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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