

## **Liver cancer: Selective Internal Radiation Therapy with SIR-Spheres® microspheres reimbursed in France**

Bonn, Germany (7 March 2019) – Sirtex Medical Europe GmbH announced that SIR-Spheres Y-90 resin microspheres will be reimbursed in France by the Health insurance for the treatment of selected patients with hepatocellular carcinoma (HCC).<sup>1</sup> HCC is the most common form of primary liver cancer. This decision results from the approval received from the *Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS)* on November 6th, 2018, which concluded that Selective Internal Radiotherapy (SIRT) with SIR-Spheres had a therapeutic benefit in this disease.<sup>2</sup> The reimbursement of SIR-Spheres will be effective from 20 March 2019 on.

The approved indication for SIR-Spheres Y-90 resin microspheres is in the palliative treatment of intermediate or advanced HCC (BCLC<sup>i</sup> stage B/C), without complete occlusion of the main portal vein, in patients with good performance status (ECOG<sup>ii</sup> score 0-1), with preserved liver function (Child-Pugh<sup>iii</sup> A-B) and who are not eligible for or have failed treatment with sorafenib<sup>iii</sup>.<sup>1</sup>

Professor Christine Silvain, Head of the Hepatology and Gastroenterology department of the University Hospital in Poitiers stated: « This reimbursement decision is excellent news. This will enlarge the therapeutic armamentarium in HCC which is a severe and frequent disease. One of the advantages of SIRT is to maintain patients' quality of life. ».

« SIRT is indeed a treatment well-tolerated by patients. This treatment can, in some cases, shrink enough the tumour(s) to make the patient eligible to surgery which is so far the most efficient treatment » added Doctor Mohamed Bouattour, hepatologist at the Beaujon Hospital – Hôpitaux Universitaires Paris Nord Val de Seine.

About 1,100 patients per year could benefit from SIRT with SIR-Spheres microspheres according to the CNEDiMTS assessment. This new reimbursed indication for SIR-Spheres microspheres add up to the one approved in 2017, for the treatment of liver metastases from colorectal cancer, in patients who are refractory or intolerant to chemotherapy and meet certain criteria.<sup>1</sup>

Anthony Dixon, Executive Vice-President of Sales & Marketing EMEA, said: « Sirtex is very pleased with the addition of this new reimbursed indication for SIR-Spheres in France. Sirtex is pursuing its commitment in extending patients' access to innovative treatments in interventional oncology. ».

### **About hepatocellular carcinoma**

Hepatocellular carcinoma is a severe and life-threatening disease.<sup>1</sup>

Every year in France, more than 10,000 patients are diagnosed with primary liver cancer. In 2018, this disease was the fifth cause of cancer-related death.<sup>3</sup> HCC represents 80 to 90% of primary liver cancer and develops mostly in patients with cirrhosis, caused mainly by viral hepatitis B or C, alcoholism or steatohepatitis (fatty liver disease).<sup>4,5</sup>

### **About Selective Internal Radiation therapy (SIRT)**

SIRT consists of introducing radioactive sources close to or directly into the tumour(s). During the treatment millions of radioactive microspheres are injected, through a catheter, in the hepatic arteries that feed the tumour(s). SIRT is performed by multidisciplinary teams that include hepatologists, interventional radiologists and nuclear medicine physicians.

## About Sirtex

Sirtex Medical is an Australian-based global healthcare company with the mission to improve the quality and longevity of patients' lives by providing innovative interventional oncology solutions. The lead product of Sirtex is SIR-Spheres Y-90 resin microspheres. Over 92,000 doses of SIR-Spheres microspheres have been delivered in more than 1,230 treatment centres for the treatment of patients with liver tumours in more than 40 countries.

SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.

For full instructions for use and important safety information, please read the package insert carefully.

- i. The BCLC staging system (Barcelona Clinic Liver Cancer) has identified 5 different patient categories taking into account the performance status, tumour characteristics, liver function (according to the Child-Pugh staging system) as well as the cancer-related symptoms: Stage 0 – very early; Stage A – early; Stage B – intermediate; Stage C – advanced; Stage D – end-stage.
- ii. The performance status ECOG score (Eastern Cooperative Oncology Group) is a scale evaluating patients' overall health and a prognostic factor. This scale runs from 0 (normal activities without restriction) to 4 (completely disabled).
- iii. The Child- Pugh score is assessing the liver function in cirrhotic patients and it helps predicting their chance of survival.

## References:

1. Arrêté du 1er mars 2019 portant modification des conditions d'inscription des microsphères d'Yttrium-90 SIR-SPHERES de la société SIRTEX MEDICAL EUROPE GmbH inscrit au titre III de la liste des produits et prestations remboursables prévue à l'article L165-1 du code de la sécurité sociale. <https://www.legifrance.gouv.fr/eli/arrete/2019/3/1/SSAS1906504A/jo/texte>
2. CNEDiMTS. SIR-Spheres, microsphères d'yttrium-90. Avis du 06 novembre 2018. [https://www.has-sante.fr/portail/jcms/c\\_2896412/fr/sir-spheres](https://www.has-sante.fr/portail/jcms/c_2896412/fr/sir-spheres)
3. Ferlay J, Ervik M, Lam F *et al.* Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. 2018 Available from: <https://gco.iarc.fr/today>, accessed [1 Mars 2019].
4. Blanc J-F, Barbare JC, Baumann A-S, *et al.* Carcinome hépatocellulaire. In: Thésaurus National de Cancérologie Digestive [Internet]. 2017. Available from: [www.tncd.org](http://www.tncd.org).
5. Galle PR, Forner A, Llovet JM, *et al.* EASL Clinical Practice Guidelines: Management of hepatocellular carcinoma. *Journal of Hepatology* 2018; **69**: 182-236.

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