Press release

New indication approved for Guerbet's Lipiodol® Ultra Fluid

Lipiodol® Ultra Fluid now approved for conventional trans-arterial chemoembolization of intermediate-stage hepatocellular carcinoma in Switzerland and in India

Villepinte (France) – June 6th, 2019 - 06:00pm (CEST) - Guerbet (GBT) announced that it has been granted approval for a new indication for Lipiodol® Ultra Fluid in Switzerland and in India for chemoembolization (cTACE) of tumors in adults with known intermediate-stage hepatocellular carcinoma (HCC).

HCC is the most common primary liver cancer and is the 4th leading cause of annual cancer death worldwide[1].

"Guerbet is proud to have received approval for this new indication for Lipiodol® Ultra Fluid. This is evidence of our commitment to making c-TACE available to as many HCC patients as possible." said **Thomas Bonnefont, Guerbet's VP for Interventional Imaging**. *"Development of these image-guided procedures is a top priority for Guerbet's Interventional Imaging Franchise as we work to enhance liver cancer patients' prognosis and quality of life worldwide."*

Lipiodol® Ultra Fluid is used for cTACE, a minimally invasive procedure which consists of mixing Lipiodol® Ultra Fluid with an anticancer drug. The mixture is injected trans-arterially in the liver as a loco-regional targeted chemotherapy for unresectable liver tumors (HCC). Lipiodol® Ultra Fluid acts as a contrast agent, a drug eluting vehicle, and a dual arterio-portal transient embolic[2].

cTACE indication is now approved in EMEA (Austria, Belgium, Czech Republic, France, Hungary, Iran, Ireland, Luxemburg, the Netherlands, Portugal, Switzerland, Turkey), APAC (Cambodia, Hong Kong, India, Mongolia, New Zealand, Philippines, South Korea, Taiwan, Thailand, Vietnam), and Latin America (Argentina, Brazil, Mexico, Peru).

HCC imaging indication is now approved in Canada, Germany and in the USA.

The approval in Switzerland and in India testifies to the Guerbet commitment to develop its Interventional Imaging franchise and invest in clinical programs and R&D to deliver enhanced and innovative interventional oncology therapies.

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[1] WHO, Globocan 2018: https://gco.iarc.fr/today/data/factsheets/cancers/11-Liver-fact-sheet.pdf

[2] Kan Z. et al., Liver anatomy: microcirculation of the liver, Sem. Intervent. Radiology 2008; 25: 77-85.

Guerbet Lipiodol® Ultra Fluid is used in cTACE procedures to treat patients with unresectable liver tumors. cTACE has been extensively studied worldwide and a systematic review of efficacy on more than 10,000 patients and safety on more than 15,000 patients has been published by Lencioni et al (2016)[3]. They concluded that survival figures of HCC patients undergoing Lipiodol TACE was in line with those reported in previous randomized controlled trials[4,5] and no new or unexpected safety concerns were identified and thus cTACE using Lipiodol remains the standard of care for HCC patients at intermediate stage. Technical recommendations have also been recently published by de Baère et al (2015)[6] and Miyayama & Matsui (2016)[7].

cTACE has been recognized as the gold standard for the treatment of patients with intermediate-stage HCC by several international clinical consensus. These consensus guidelines unanimously recommend cTACE as the standard-of-care for patients with intermediate-stage HCC[8,9,10]. cTACE has strong recommendation and high leave of evidence for patients at BCLC stage B in European guideline[9]. Median survival for untreated patients at an intermediate-stage is 16 months, while cTACE extended median survival of around 40 months in well-selected candidates with a state-of-the-art technique and a super-selective approach[9], representing 24 additional months. Consequently, treatment with cTACE is constantly increasing on all continents, with more than 400,000 patients being treated every year[11].

About Lipiodol® Ultra Fluid

Lipiodol® Ultra Fluid (ethyl esters of iodized fatty acids of poppyseed oil) was initially developed for diagnostic radiology in indications including liver lesion diagnosis, lymphography and hysterosalpingography, and then used in interventional radiology for conventional trans-arterial chemo-embolization (cTACE) procedures of multinodular hepatocellular carcinoma, where Lipiodol® Ultra Fluid was used as a procedure visualizer (contrast agent), a drug vehicle (drug carrier), and an embolic. The approved indications for Lipiodol® Ultra Fluid may vary according to countries. Please refer to local SmPC for further information.

[3] Lencioni R, de Baère T, Soulen M et al. Lipiodol Transarterial Chemoembolization for Hepatocellular Carcinoma: A Systematic Review of Efficacy and Safety Data. Hepatology 2016; 64: 106-116.

[4] Llovet JM, Real MI, Montana X, et al. Arterial embolisation or chemoembolisation versus symptomatic treatment in patients with unresectable hepatocellular carcinoma: a randomised controlled trial. Lancet 2002; 359: 1734-1739.

[5] Lo CM, Ngan H, Tso WK, et al. Randomized controlled trial of transarterial lipiodol chemoembolisation for unresectable hepatocellular carcinoma. Hepatology 2002; 35: 1164-1171.

[6] De Baère T, Arai Y, Lencioni R et al Treatment of liver tumors with Lipiodol TACE: technical recommendations from expert's opinion. Cardiovasc Intervent Radiol 2015; 39: 334–343.

[7] Miyayama S, Matsui O. Superselective conventional transarterial chemoembolization for hepatocellular carcinoma: rationale, technique and outcome. J Vasc Interv Radiol 2016; 27: 1269-1278.

[8] Japan Society of Hepatology, Recommendation, Chapter 5 (CQ44, page 105); Hepatology Research 2010; 40 (Suppl.1): 96-112

[9] EASL Clinical Practice Guidelines: Management of hepatocellular carcinoma. European Association for the Study of the Liver. J Hepatol 2018, https://doi.org/10.1016/j.jhep.2018.03.019

[10] Marrero JA, Kulik LM, Sirlin CB et al. Diagnosis, Staging, and Management of Hepatocellular Carcinoma: 2018 Practice Guidance by the American Association for the Study of Liver Diseases. Hepatology, 2018; 68: 723-750.

[11] Guerbet data 1997-2017

About Guerbet

Guerbet is a pioneer in the contrast-agent field, with more than 90 years' experience, and is a leader in medical imaging worldwide. It offers a comprehensive range of pharmaceutical products, medical devices and services for diagnostic and interventional imaging, to improve the diagnosis and treatment of patients. With 8% of revenue dedicated to R&D and more than 200 employees distributed amongst its four centers in France, Israel and the United States, Guerbet is a substantial investor in research and innovation. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €790 million in revenue in 2018. For more information about Guerbet, please visit www.guerbet.com.

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