



ANSM approves Lipiodol® Ultra-Fluid for visualization, localization and vectorization of hepatocellular carcinoma during trans-arterial chemoembolization

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Guerbet (GBT) announces the approval of Lipiodol® Ultra-Fluid by the French National Agency for Medicines and Health Products (ANSM) for selective hepatic intra-arterial injection for visualization, localization and vectorization during chemoembolization of tumors in adults with known, intermediate-stage hepatocellular carcinoma (HCC).

HCC is the most common primary cancer and is the second biggest cause of death due to cancer worldwide¹.

“Guerbet enters a new phase in obtaining this indication for Lipiodol® in France for conventional trans-arterial chemoembolization (cTACE). This procedure is carried out to deposit, in contact with the tumor, active substances which fight against the development of primary cancers in inoperable patients. The development of these minimally invasive, image-guided procedures is the new priority of Guerbet’s Interventional Radiology and Theranostic division to enhance patient prognosis and quality of life”, commented Yves L’Epine, Guerbet’s CEO.

This approval follows that granted by the Japanese authorities in November 2013 for the treatment by conventional trans-arterial chemoembolization of HCC² and that granted by the US authorities in April 2014 for the imaging of HCC³. It reflects Guerbet’s strategy to develop its IRT division, which should generate around € 30 million in sales in 2014 (at constant exchange rates). Guerbet’s ambition is to double the division’s sales by 2017 (2017 vs. 2014, at constant exchange rates).

Worldwide over 100 clinical studies have been published in the scientific literature, including 12 randomized clinical trials on a total of over 10,000 patients presenting with an intermediate stage HCC.

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Recently three international recommendations in Europe, in the United States and in Japan established cTACE as the reference treatment for patients presenting with an intermediate-stage HCC. These consensual recommendations unanimously accredited the use of cTACE as the benchmark treatment for patients with known intermediate-stage HCC^{4,5,6}.

These recommendations were formulated with a level of proof of 1iiA and a recommendation grade of 1A in the European directives⁵.

These recommendations stipulate that the life expectancy of inoperable HCC patients is increased, on average, by 16 to 20 months, thanks to cTACE. In recent clinical trials, using the most selective catheterization techniques, life expectancy was improved to 45 months.

Consequently treatment by cTACE is constantly increasing on all continents, with an extra 500,000 patients being treated every year⁷.

About cTACE

Conventional Trans-arterial Chemoembolization or cTACE is a minimally invasive procedure which consists of mixing Lipiodol® Ultra-Fluid with an anti-cancer agent and injecting this mixture in the liver trans-arterially by targeted regional chemotherapy. Lipiodol® Ultra-Fluid acts both as a contrast agent, a vehicle, an eluent for the cancer drug and a transient vascular embolization agent⁸. cTACE was performed for the first time in Japan in 1982 and has since been successfully used in Asia, Europe, in the Middle East, Africa and North America.

About Lipiodol®

Lipiodol® Ultra-Fluid (ethyl esters of iodized fatty acids of poppyseed oil) was originally developed for diagnostic radiology in indications including the diagnosis of hepatic lesions, lymphography and hysterosalpingography. Subsequently the product was used in interventional radiology for the treatment using conventional trans-arterial chemoembolization (cTACE) of multinodular hepatocellular carcinoma in which Lipiodol® Ultra-Fluid is used as for its properties a contrast agent, vehicle for active substances and embolization agent. Lipiodol® Ultra-Fluid is a registered Guerbet trade mark. For full information about Lipiodol® Ultra-Fluid, in particular warnings and precautions for use, please consult the [summary of product characteristics](#) in force in France.

About Guerbet

A pioneer in the field of contrast agents with more than 80 years of experience, Guerbet is the only pharmaceutical group fully dedicated to medical imaging worldwide. As such it has a complete offering of contrast agents for X-ray and MRI and for interventional radiology, along with a range of injectors and related medical equipment to provide improved diagnosis and treatment of patients. To promote the discovery of new products and assure future growth, Guerbet devotes significant resources to research and development every year (approximately 10% of sales). Guerbet (GBT) is listed on NYSE Euronext

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Paris (Eurolist Segment B – Mid Caps) and had sales of €390 million in 2013 with a total workforce of 1,485 employees, with over 1,000 in France.

For additional information about Guerbet please go to www.guerbet.com.

References

¹ WHO – Globocan 2012 (IARC) Section of Cancer Surveillance (9/7/2014).

² Guerbet press release (27/11/2013).

³ Guerbet press release (10/04/2014).

⁴ Japan Society of Hepatology, Recommendation, Chapter 5 (CQ44, page 105); Hepatology Research 2010; 40 (Suppl.1): 96-112.

⁵ EASL-EORTC Clinical Practice Guidelines: Management Association of Study of Liver Disease & European Organization Cancer); Journal of Hepatology 2012 vol. 56 j 908-943.

⁶ AASLD Practice Guidelines; American Association for Study of the Liver Diseases; HEPATOLOGY, Vol. 53, No. 3, 2011.

⁷ Guerbet data 1997 to 2013.

⁸ Kan et al., Seminars in Interventional Radiology 2008; 25 (2): 7785.

Forward-looking statements

This press release may contain forward-looking statements based on current assumptions and forecasts made by Guerbet Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performances of the company and the estimates given here. These factors include those discussed in Guerbet's public reports which are available on the Guerbet website at www.guerbet.com. The company assumes no liability whatsoever to update these forward-looking-statements or to conform them to future events or developments.

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