Press Release

FDA Approves Lipiodol® (Ethiodized Oil) Injection for Imaging of Tumors in Adults with Known Hepatocellular Carcinoma (HCC)

Guerbet LLC, USA (April 10, 2014)

Princeton (NJ), Guerbet, a pioneer in the field of contrast agents for medical imaging announced that Lipiodol® was approved by the US Food and Drug Administration pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act indicated for selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC). HCC is the most common primary liver tumor and represents the third-leading cause of cancer-related death in the world[1], with prevalence in US estimated to affect in the range of 35,000 U.S. patients in 2013[2].

As previously announced in October 2013, Lipiodol has received an orphan-drug designation for management of patients with known HCC.

"Guerbet is pleased to have been granted approval for use of Lipiodol in patients with known HCC. This product has been supplied during the past three years under a temporary importation program. Guerbet's efforts to improve the availability of Lipiodol in the USA are in line with our company mission offering reliable and innovative solutions to improve the efficacy of Interventional Radiology procedures", commented Massimo Carrara, Guerbet US General Manager.

This approval was received shortly after FDA granted approval to a new site to manufacture Lipiodol, validated for US distribution only (Jubilant HollisterStier, Canada).

"The additional indication approved by FDA is a major milestone on the ambitious approach taken by the company to keep the product accessible for US patients to assist in the management of this devastating disease. We are pleased to receive FDA authorization which assures continuous accessibility to this drug to many HCC patients

[1] Altekruse *et al.* Hepatocellular Carcinoma Incidence, Mortality, and Survival Trends in the United States From 1975 to 2005. J Clin Oncol. 2009 March 20; 27(9): 1485–1491.
[2] Data on File, Guerbet LLC

across America", said Corina Harper, Guerbet Director of North America Medical and Regulatory Affairs.

Guerbet plans to transition from the temporary importation program as soon as product from the newly approved manufacturing plant will be available in the US. For more information about the temporary importation program, please see the Dear Healthcare Professional Letter.

Lipiodol is contraindicated in patients with hypersensitivity to Lipiodol, hyperthyroidism, traumatic injuries, recent hemorrhage or bleeding.

Important Safety Information

WARNING: FOR INTRALYMPHATIC, INTRAUTERINE AND SELECTIVE HEPATIC INTRA-ARTERIAL USE ONLY

Pulmonary and cerebral embolism can result from inadvertent intravascular injection or intravasation of Lipiodol. Inject Lipiodol slowly with radiologic monitoring; do not exceed recommended dose (5.1).

Lipiodol is indicated for hysterosalpingography in adults, lymphography in adults and children, and selective hepatic intra-arterial use for imaging tumors in adults with known HCC.

Contraindications:

Lipiodol hysterosalpingography is contraindicated in pregnancy, acute pelvic inflammatory disease, marked cervical erosion, endocervicitis and intrauterine bleeding, in the immediate pre-or postmenstrual phase, or within 30 days of curettage or conization.

Lipiodol lymphography is contraindicated in right to left cardiac shunt, advanced pulmonary disease, tissue trauma or hemorrhage, advanced neoplastic disease with expected lymphatic obstruction, previous surgery interrupting the lymphatic system, or radiation therapy to the examined area.

Lipiodol selective hepatic intra-arterial injection is contraindicated in the presence of dilated bile ducts unless external biliary drainage was performed before injection.

Warnings and Precautions:

Pulmonary and cerebral embolism may occur immediately or after a few hours to days from inadvertent systemic vascular injection or intravasation of Lipiodol. Avoid use in

patients with severely impaired lung function, cardiorespiratory failure or right-sided cardiac overload.

Anaphylactoid and anaphylactic reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following Lipiodol administration. Avoid use in patients with a history of sensitivity to other iodinated contrast agents, bronchial asthma or allergic disorders because of an increased risk of a hypersensitivity reaction to Lipiodol.

Lipiodol hepatic intra-arterial administration can exacerbate chronic liver disease.

Iodinated contrast media can affect thyroid function because of the free iodine content and can cause hyperthyroidism or hypothyroidism in predisposed patients.

Adverse Reactions:

Adverse reactions caused by Lipiodol include hypersensitivity reactions, pulmonary and cerebral embolism, pulmonary dysfunction, exacerbation of liver disease, procedural complications, abdominal pain, fever, nausea, vomiting, and thyroid dysfunction.

For more information about Lipiodol, other approved indications including full Boxed WARNING, please see the Full Prescribing Information.

About Lipiodol

Discovered in 1901 by Marcel Guerbet, Lipiodol is approved for use in over 47 countries in Europe, Asia, Africa, Middle East, North and South America. Lipiodol is the first and only oil-based iodinated contrast medium for radiology, launched in France in 1921[3]. It is estimated that more than 200 million of Lipiodol doses have been administered worldwide[4]. The contrast agent was first launched in the United States in 1954 and marketed as Ethiodol®. Guerbet acquired the NDA from Nycomed, US, Inc. in 2010. The approved indications for Lipiodol may vary between countries. Lipiodol is available by prescription only. Lipiodol is registered by the U.S. Patent and Trademark Office by Guerbet.

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 products 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 the NYSE Euronext Paris (Eurolist Segment B – Mid Caps) and had sales of €390 million in 2013 with a total workforce of 1,485 employees. For additional information about Guerbet please go to www.guerbet.com.

[3, 4] Data on File, Guerbet LLC

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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