



PRESS RELEASE

FDA Grants Orphan Drug Designation to Lipiodol® (Ethiodized Oil) Injection for Management of Patients with Known Hepatocellular Carcinoma (HCC)

Guerbet LLC, USA (October 21, 2013)

Guerbet, a pioneer in the field of contrast agents with more than 80 years of experience, announced that it has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) for Lipiodol® (ethiodized oil) Injection for management of patients with known hepatocellular carcinoma (HCC).

Hepatocellular carcinoma prevalence in US is estimated to affect approximately 35,000 U.S. patients in 2013. Orphan Drug Designation is granted to drug therapies intended to treat diseases or conditions that affect fewer than 200,000 people in the United States. Orphan Drug Designation entitles the sponsor to clinical protocol assistance with the FDA, as well as federal grants, tax credits, and potentially a seven year market exclusivity period.

"We are very pleased to have been granted an orphan drug designation for Lipiodol®," commented Dr. Yves L'Epine, Chief Executive Officer of Guerbet. "Patients with known HCC may have Lipiodol® approved as part of their disease management as an option. We are excited to further expand development of Lipiodol® to include the drug's potential use for selective hepatic intraarterial injection in computed tomography of the liver to visualize and localize lesions in adults with known HCC".

Lipiodol® is currently under FDA evaluation for safety and efficacy with a proposed indication "for selective hepatic intraarterial use in computed tomography of the liver to visualize and localize lesions in adults with known HCC".

About Lipiodol®

Discovered in 1901 by Marcel Guerbet, Lipiodol® is now commercialized widely in over 47 countries in Europe, Asia, Africa, Middle East, North and South America. The approved indications for Lipiodol® may vary between countries.

About Guerbet

Guerbet is the only pharmaceutical group fully dedicated to medical imaging worldwide. As such it has a complete offering of contrast products for Xray 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 Paris (Eurolist Segment B – Mid Caps) and had sales of €403 million in 2012 with a total workforce of 1,400 employees.

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Lipiodol® is registered in U. S. Patent and Trademark Office by Guerbet.