PRESS RELEASE

U.S. Food and Drug Administration (FDA) grants Breakthrough Device status to the Guerbet innovation: LIPIOJOINT

Villepinte France, February 10th, 2025: Guerbet (FR0000032526 GBT), a global leader in medical imaging solutions, announced today that **the US Food and Drug Administration (FDA) has granted Breakthrough Device designation to LIPIOJOINT**, an innovative transient liquid embolic agent designed to alleviate pain and the related burden of reduced mobility in patients with knee osteoarthritis (KOA)[1].

FDA's Breakthrough designation is awarded to certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions[2]. This recognition highlights the potential of LIPIOJOINT as a minimally invasive and targeted approach for KOA patients who have not found relief through non-surgical treatment modalities.

"Being part with LIPIOJOINT of the FDA breakthrough program is a major milestone for Guerbet but most importantly for patients suffering from Osteoarthritis. Working closely with the US administration will give a unique opportunity to bring an innovative approach aiming to release pain for a large part of the population. A unique collaboration for a medical unmet need" said Dan Raffi, Global Chief Commercial Officer & President, France, Guerbet.

About LIPIOJOINT

LIPIOJOINT is a novel transient liquid embolic agent under the development by Guerbet for Genicular Artery Embolization (GAE), a minimally invasive procedure performed by interventional radiologist. The product will selectively embolize the knee synovial neovessels that appear in knee osteoarthritis and aims to alleviate pain and the related burden of reduced mobility in knee osteoarthritis patients.

Encouraging clinical data from the Lipiojoint-1 study (NCT04733092)[2], led by Professor Marc Sapoval, Head of the Vascular and Oncological Interventional Radiology Department at Hôpital Georges Pompidou (Paris, France), demonstrated promising outcomes in pain reduction and knee function.

Guerbet is committed to driving innovation in interventional radiology and developing novel solutions that address unmet medical needs. With LIPIOJOINT, the company is advancing the field of embolization procedure that can help patients suffering from knee osteoarthritis who have exhausted non-surgical treatment options.

[1] Internal source document FDA Designation letter
[2] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

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[3] Marc Sapoval,et al. Genicular artery embolization for knee osteoarthritis: Results of the LipioJoint-1 trial, Diagnostic and Interventional Imaging, Volume 105, Issue 4, 2024, Pages 144-150, ISSN 2211-5684, https://doi.org/10.1016/j.diii.2023.12.003

About Guerbet

Guerbet is a global leader in medical imaging, dedicated to improving patient care through innovation. With nearly a century of expertise, the company offers a comprehensive portfolio of pharmaceutical products, medical devices, and AI-driven solutions for diagnostic and interventional imaging. Guerbet invests 9% of its annual revenue in research and development, with dedicated innovation centers in France and the United States. The company (GBT) is publicly traded on Euronext Paris and reported €841 million in revenue in 2024.

For more information, visit: www.guerbet.com

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