**Press release**

# Gadopiclenol Marketing Authorization dossier submissions accepted for review by EMA and FDA

## Priority Review granted by US-FDA
## March 28, 2022

**Villepinte (France), March 29 2022** – Guerbet (FR0000032526 GBT), a global leader in medical imaging offering a comprehensive range of pharmaceutical products, medical devices, and digital and artificial intelligence (AI) solutions for diagnostic and interventional imaging, has recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and a Centralized Application for Marketing Authorization to the European Medicine Agency (EMA) for Gadopiclenol, an investigational macrocyclic gadolinium-based contrast agent (GBCA). Those applications have been accepted for review by EMA and FDA on February 24 and March 28, respectively.

In addition, the US-FDA has accepted the request for Priority Review with a goal date for taking action on an application by September 21, 2022. Priority review designation is assigned to applications for drugs that provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies.

The dossiers are supported by the data from two Phase III studies for the investigational macrocyclic GBCA, Gadopiclenol completed in March 2021. The results from these Phase III studies are available on the ClinicalTrials.gov database (see below).

### About Gadopiclenol

Gadopiclenol is an investigational macrocyclic gadolinium-based contrast agent developed by Guerbet's Research & Development team. The efficacy and safety of Gadopiclenol have been evaluated as part of the company's clinical development plan with a view to obtaining worldwide marketing authorization. No regulatory authority has evaluated the clinical study data for this product to date. Details on Phase III clinical trials are available on the www.ClinicalTrials.gov.

- Efficacy and Safety of Gadopiclenol for Central Nervous System (CNS) Magnetic Resonance Imaging (MRI) - Full Text View - ClinicalTrials.gov
- Efficacy and Safety of Gadopiclenol for Body Magnetic Resonance Imaging (MRI) Full Text View -ClinicalTrials.gov

## About Guerbet

At Guerbet, we build lasting relationships so that we enable people to live better. That is our purpose. We are a global leader in medical imaging, offering a comprehensive range of pharmaceutical products, medical devices, and digital and AI solutions for diagnostic and interventional imaging. As pioneers in contrast products for 95 years, with more than 2,600 employees worldwide, we continuously innovate and devote 8%-10% of our revenue to research and development in five centers in France, Israel, and the United States. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €732 million in revenue in 2021. For more information, please visit www.guerbet.com.

## Forward-looking statements

This press release may contain statements of a forward-looking nature, based on assumptions and predictions made by the management of the Guerbet group. Various known and unknown risks, uncertainties and other factors could lead to marked differences between the future results, financial situation, development and performances of the company, and the estimates made here. These factors include those mentioned in the public reports of Guerbet, available on its website www.guerbet.com. The company assumes no responsibility whatsoever in relation to the updating of these forward-looking statements, or how they correspond to future events or developments.

## Media relations

**Guerbet Global**
ACTIFIN
Marie-Ji-In PRADERE
+33 (0)1 56 88 11 21 / mpradere@actifin.fr

SOURCE Guerbet