



## Gadopiclenol: positive results for Phase III clinical trials

- Gadopiclenol is a high-relaxivity macrocyclic contrast agent used for magnetic resonance imaging (MRI).
- Its diagnostic efficacy and safety have been evaluated in two Phase III clinical studies with a dose of gadolinium reduced by half compared to products already available on the market.
- Guerbet is planning to make regulatory submissions from early 2022 in a wide range of indications in adults and children from 2 years of age.

**Villepinte (France), March 24, 2021 (8 a.m. CET)** – Guerbet (FR0000032526 GBT), a world leader in medical imaging, today announced positive results from two Phase III clinical studies comparing the diagnostic efficacy and safety of Gadopiclenol to Gadobutrol in a wide range of indications, covering the central nervous system and various other anatomical areas (head and neck, thorax, abdomen, pelvis, musculoskeletal system).

A total of 560 patients were recruited for these two studies in over 60 hospital medical imaging departments in 13 countries.

The endpoints were met in terms of the diagnostic benefit of injecting Gadopiclenol (0.05 mmol/kg) during MRI examinations, based on: 1/ the superiority of the examination with Gadopiclenol compared to the examination with no contrast agent; and 2/ the non-inferiority of Gadopiclenol (0.05 mmol/kg) compared to Gadobutrol (0.1 mmol/kg) for the visualization and detection of lesions of the central nervous system and in the other anatomical areas studied.

In addition to these Phase III trials, a study was conducted on 80 children between 2 and 17 years of age in 19 centers in five European countries. This study showed that the pharmacokinetic profile of Gadopiclenol at 0.05 mmol/kg in children was similar to that of adults. It will therefore be possible to extrapolate the efficacy of Gadopiclenol to the pediatric population based on data collected in adult patients.

## Press release

No major safety signals were reported during the development of Gadopiclenol, and the adverse reactions reported during the two Phase III studies were similar for both of the products administered.

*“We are very happy with the results of these studies, which demonstrate the diagnostic value and good tolerance of Gadopiclenol during an MRI examination in adults and children. By using a lower dose of gadolinium in clinical practice, we hope this macrocyclic contrast agent will become a ‘best-in-class’ diagnostic solution for doctors and their patients.”* said David Hale, CEO of Guerbet.

All this data will serve as a basis for regulatory submissions, which will begin in the United States and in the European Union (EU) early 2022.

### About the Phase III clinical trials

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Details on these two clinical trials are available in the ClinicalTrials.gov database:

- [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 Gadopiclenol

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Gadopiclenol is a new macrocyclic gadolinium-based contrast agent with high relaxivity (contrast power), designed and developed by Guerbet’s R&D 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 study data for this product to date.

### About Guerbet

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Guerbet is a leader in medical imaging worldwide, offering a wide range of pharmaceutical products, medical devices, digital and AI solutions for diagnostic and interventional imaging, to improve the diagnosis and treatment of patients. A pioneer since 95 years in the field of contrast media with over 2,600 people globally, Guerbet is continuously innovating with 10% of revenue dedicated to Research & Development and four centers in France, Israel and the United States. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €712 million in revenue in 2020. For more information about Guerbet, please visit [www.guerbet.com](http://www.guerbet.com).

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