PRESS RELEASE

Guerbet
CHMP grants positive opinion for Elucirem™ (gadopiclenol) pediatric indication extension under two years of age

Villepinte, December 19th, 2025: GUERBET (FR0000032526 GBT) announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a **positive opinion** recommending the approval of **Elucirem™ (gadopiclenol)** for contrast-enhanced- MRI in children from birth.

If approved by the European Commission, **Elucirem™ (gadopiclenol)** will be indicated in adults and in children from birth, for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of:

- the brain, spine, and associated tissues of the central nervous system (CNS);
- the liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system.

For these indications, an MRI examination with **Elucirem™(gadopiclenol)** requires half the conventional gadolinium dose compared to that required with existing nonspecific contrast agents, thus answering a major concern of practitioners about gadolinium exposure.[2], [3], [4]

This extension will mark a major step forward in improving diagnostic imaging for young patients and reflects Guerbet's continued commitment to innovation and patient safety.

The European Commission is expected to issue its decision in February 2026.

Supporting a growing clinical need in pediatric imaging
Magnetic resonance imaging plays a crucial role in the care pathway of children with neurological, oncological, or inflammatory diseases.
Nearly 400,000 children and adolescents (ages 0–19) are diagnosed with cancer every year, [5] often requiring repeated MRI scans for diagnosis, treatment monitoring, and long-term surveillance.
In this context, the need for an efficient contrast agent that also reduces cumulative gadolinium exposure is particularly critical for ensuring safer long-term- imaging in young patients.

A rigorous clinical design ensuring safety and efficacy demonstration

Commenting on the clinical program, **Philippe Bourrinet**, Vice-president Development, Medical & Regulatory Affairs and Chief Pharmaceutical officer of the Guerbet Group, stated:
"*Our new pediatric clinical study in pediatric patients aged less than 2 years allowed to demonstrate that the pharmacokinetic profile, safety and efficacy of gadopiclenol was comparable to the one known in older pediatric patients and in adults. For children requiring repeated MRI examinations, the reduction in Gadolinium cumulative exposure during liefetime represents a major step forward in safety and quality of care".*

GBCA: Gadolinium-Based Contrast Agent

1 Robic C et al. Invest Radiol. 2019;54(8):475-484.

2 PRAC, European Medicines Agency, 2017

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3 FDA Drug Safety Communication, 2017

4 Brunjes et al. Water Research, 2020

5 Steliarova-Foucher E, Colombet M, Ries LAG, et al. International incidence of childhood cancer, 2001-10: a population-based registry study. Lancet Oncol. 2017;18(6):719-731.

About Guerbet

At Guerbet, we build lasting relationships to enable better living. This 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.
Pioneers in contrast agents for 99 years, with 2,905 employees worldwide, we continuously innovate and dedicate 9% of our revenue to Research & Development across four centers in France and the United States. Guerbet (GBT) is listed on Euronext Paris, Compartment B, and achieved €841 million in revenue in 2024.
For more information, please visit www.guerbet.com.

The Guerbet and Bracco Imaging collaboration

Bracco Imaging and Guerbet in December 2021 entered a worldwide collaboration on Gadopiclenol manufacturing and research and development activities. Gadopiclenol will be commercialized independently under separate brands. Both Guerbet and Bracco Imaging each own valuable intellectual property on Gadopiclenol. Furthermore, after an agreed transition period when Guerbet manufactures Gadopiclenol for both Guerbet and Bracco, both companies will manufacture the Gadopiclenol active ingredient and finished product.

The strategic collaboration is expected to accelerate access to Gadopiclenol and deliver innovation, as well as better care to patients and caregivers alike.

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