PRESS RELEASE

Guerbet

The CHMP issues an opinion in favour of granting an EU marketing authorisation for Elucirem™ (Gadopiclenol) with the indication of use for magnetic resonance imaging with contrast enhancement in adults and children aged 2 years and over

If approved by the European Commission, Elucirem™ (Gadopiclenol) will mark a step forward in innovation in MRI contrast media, thus answering to the Health authorities recommendation and concerns of patients and radiologists in Europe.

An MRI exam with Elucirem™ requires half the dose of gadolinium compared to existing non-specific contrast products.[1, 2, 3]

This recommendation is based on two phase III studies available on ClinicalTrials.gov (PICTURE and PROMISE).

Approved by the FDA in September 2022, Elucirem™ is produced in France and in the USA.

Villepinte, France, 12 october 2023: *The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion concerning the granting of a marketing authorisation for Elucirem™ (Gadopiclenol) in the European Union (EU) for use in adults and children aged 2 years and over for MRI with contrast enhancement. The European Commission is expected to issue its decision by the end of 2023. Elucirem™ was approved by the United States Food and Drug Administration in September 2022.*

Elucirem™ (Gadopiclenol) is a macrocyclic gadolinium-based contrast agent with high relaxivity, indicated in adults and children 2 years and older for magnetic resonance imaging (MRI) with contrast enhancement of the CNS (brain, spine, and surrounding tissues) and several body organs (liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system).

"The efficacy and safety of Gadopiclenol have been assessed as part of the clinical development plan conducted by Guerbet with the aim of obtaining

[1] *PRAC, European Medicines Agency, 2017*
[2] *FDA Drug Safety Communication, 2017*
[3] *Brunjes et al. Water Research, 2020*

Contacts presse :

Guerbet
Claire Lauvernier, Directrice de la Communication +33.6.79.52.11.88 / claire.lauvernier@guerbet.com

LauMa
Mathilde Birembaux, +33.6.82.34.25.38 / mathilde.birembaux@lauma-communication.com
Laurent Mignon, +33.6.10.17.54.84 / laurent.mignon@lauma-communication.com

www.guerbet.com

Marketing Authorisations worldwide"
explains **Philippe Bourrinet**, Vice-President Development, Medical & Regulatory Affairs and Responsible Pharmacist for the Guerbet Group.
"The positive opinion from the CHMP is very good news for radiologists and patients in Europe."

The positive opinion from the CHMP is essentially based on data from two phase III clinical trials completed in March 2021. They demonstrated that Elucirem™ provided non-inferior results in brain and whole-body MRIs in comparison with Gadobutrol, although half the dose of gadolinium was administered.[4, 5].

The assessment criteria were met in terms of diagnostic benefit of the MRI examination with injection of Gadopiclenol (0.05 mmol/kg) based on two criteria:
- the superiority of the examination with contrast product versus no contrast product,
- the non-inferiority of Gadopiclenol (0.05 mmol/kg) compared to Gadobutrol (0.1 mmol/kg), for the visualisation and detection of lesions of the central nervous system and other anatomical territories studied.

"This positive opinion from the CHMP,
if it results in the granting of a MA by the European Commission
at the end of 2023, will bring European patients and health professionals
an unprecedented innovation in diagnostic imaging."
concludes **David Hale**, CEO, Guerbet.

About Gadopiclenol
Gadopiclenol, initially invented by Guerbet, with subsequent contribution of Bracco IP, is a new macrocyclic gadolinium-based contrast agent (GBCA) with high relaxivity. The efficacy and safety of Gadopiclenol have been evaluated in MRI of the central nervous system, head and neck, thorax, abdomen, pelvis, and musculoskeletal system (for USA reference, please see USA- approved prescribing information here). Details of phase III clinical trials are available in the database 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 -gov*

[4] *https://classic.clinicaltrials.gov/ct2/show/NCT03996447?term=gadopiclenol&draw=2&rank=2*
[5] *https://www.clinicaltrials.gov/ct2/show/NCT03986138?term=Gadopiclénol&draw=2&rank=1*

Contacts presse :

Guerbet
Claire Lauvernier, Directrice de la Communication +33.6.79.52.11.88 / claire.lauvernier@guerbet.com

LauMa
Mathilde Birembaux, +33.6.82.34.25.38 / mathilde.birembaux@lauma-communication.com
Laurent Mignon, +33.6.10.17.54.84 / laurent.mignon@lauma-communication.com

About Guerbet

At Guerbet, we build lasting relationships to enable people to live better lives. This is our Company Purpose (or Raison d'Être in French). We are a global leader in medical imaging, proposing a wide range of pharmaceutical products, medical devices, digital and AI solutions for diagnostic and interventional imaging. A pioneer for 95 years in the field of contrast products, with more than 2,600 employees worldwide, we continuously provide innovative solutions and devote 10% of our sales to Research & Development in four centres in France, Israel and the USA. Guerbet (GBT) is listed in compartment B of Euronext Paris and our turnover was 753 million euros in 2022. For more information, please visit www.guerbet.com.

About the Guerbet / 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.

Forward-looking disclaimer

This press release may contain forward-looking statements based on the assumptions and forecasts of Guerbet Group Management. They involve known and unknown risks, uncertainties and other factors, which may result in a material difference between the results, financial situation, outcome and future performance of the Group and those presented in these forward-looking statements. These factors include those mentioned in Guerbet's public documents and available on its website www.guerbet.com. The Group expressly refutes any obligation to publish an update or revise any forward-looking statements contained in this press release in the light of new events or developments.

Contacts presse :

Guerbet
Claire Lauvernier, Directrice de la Communication +33.6.79.52.11.88 / claire.lauvernier@guerbet.com

LauMa
Mathilde Birembaux, +33.6.82.34.25.38 / mathilde.birembaux@lauma-communication.com
Laurent Mignon, +33.6.10.17.54.84 / laurent.mignon@lauma-communication.com