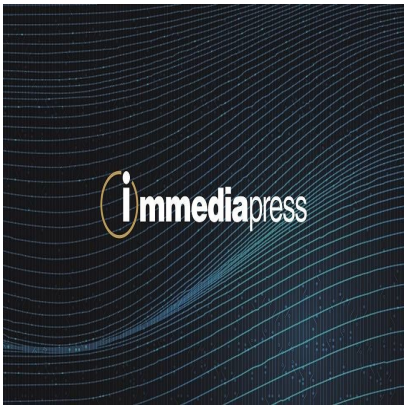

New indication in children from birth for Guerbetâ??s half-dose GBCA, Eluciremâ?¢ (Gadopiclenol) approved by European Commission

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

VILLEPINTE, France, Jan. 27, 2026 /PRNewswire/ â?? Guerbet (FR0000032526 GBT), a global specialist in contrast media and solutions for medical imaging, is delighted to announce the approval by European Commission of a new indication in children from birth for its macrocyclic high-relaxivity gadolinium-based contrast agent, Eluciremâ?¢ (gadopiclenol) in the European Union (EU).

Born of Guerbet innovation, Eluciremâ?¢ (Gadopiclenol) is the first gadolinium-based contrast agent with the highest relaxivity, in comparison to other available gadolinium-based contrast agents (GBCA) [1]. Eluciremâ?¢ was initially approved in the EU in December 2023. It is produced in France and in the USA and is marketed by Guerbet in vials and prefilled syringes.

In the European Union, Eluciremâ?¢ is indicated in adults and in children now 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:

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

â?• The new indication of Eluciremâ?¢ for pediatric patients from birth reflects our commitment to combining medical innovation and patient safety. European radiologists will be able to perform contrast-enhanced MR imaging using half the conventional gadolinium dose, which is critical for patients, especially those requiring serial MRI examinations during their lifetime, as it reduces cumulative gadolinium exposureâ?•, explains ValÃ©rie Brissart, Guerbet SVP Diagnostic Imaging.

â??Children are a very vulnerable groupâ??theyâ??re still developing, and we want to be as safe as possible with everything we do. One key asset of Eluciremâ?¢ is that, thanks to its higher relaxivity, we

can get very good image quality using only half the conventional gadolinium dose. That makes a real difference in terms of amount of gadolinium injected, especially for these young patients, without losing diagnostic accuracy.â?•, says Dr. Emilio J Inarejos Clemente, Director and Pediatric radiologist, Hospital Sant Joan de DÃ©u in Barcelona (Spain).

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 â?¬841 million in revenue in 2024. For more information, please visit www.guerbet.com.

About Gadopiclenol

Gadopiclenol, initially invented by Guerbet, with the subsequent contribution of intellectual property held by Bracco, is a new gadolinium-based macrocyclic contrast agent (GBCA) with high relaxivity. The efficacy and safety of Gadopiclenol have been evaluated in MRI central nervous system, head and neck, chest, abdomen, pelvis and musculoskeletal system.

The European Summary of Product Characteristics of Eluciremâ?¢ 0.5mmol/Ml solution for injection can be found at:https://www.ema.europa.eu/en/documents/product-information/elucirem-epar-product-information_en.pdf

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 is 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.

GBCA: Gadolinium-Based Contrast Agent

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

2 PRAC, European Medicines Agency, 2017

3 FDA Drug Safety Communication, 2017

4 Brunjes et al. Water Research, 2020

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