

Guerbet and Bracco Imaging Announce a Global Strategic Collaboration Agreement for Gadopiclesol

Companies will collaborate on manufacturing and research and development for future indications, and will commercialize Gadopiclesol independently under separate brands

Gadopiclesol is a next-generation, macrocyclic contrast agent with high-relaxivity, intended to improve lesion detection and visualization in MRI, with lower doses of gadolinium compared to other agents on the market

Guerbet and Bracco Imaging will seek regulatory approval to market Gadopiclesol in the United States and the European Union in 2023, with other geographies to follow

December 14, 2021 (7:00 a.m. CET) – 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, and Bracco Imaging, an innovative world leader delivering end-to-end products and solutions through a comprehensive portfolio inclusive of precision diagnostic imaging modalities, today announced they have signed a global collaboration for Gadopiclesol, a next-generation magnetic resonance imaging (MRI) contrast agent. This global collaboration will result in Guerbet and Bracco Imaging commercializing the product independently under different brand names. The companies will also collaborate on manufacturing, as well as research and development for future indications. Financial terms of the transaction are not disclosed.

A next-generation, macrocyclic gadolinium-based contrast agent with high relaxivity, Gadopiclesol is intended to improve lesion detection and visualization in MRI scanning, with lower doses of gadolinium compared to other agents already on the market. In March 2021, positive results from two Phase III studies comparing the diagnostic efficacy and safety of Gadopiclesol, which uses half the dose of gadolinium compared to Gadobutrol, in a wide range of indications, covering the central nervous system and various other anatomical areas (head and neck, thorax, breast, abdomen, pelvis, musculoskeletal system) were published by Guerbet. Both Guerbet and Bracco Imaging each own valuable intellectual property relating to Gadopiclesol.

“Gadopiclesol will be an excellent extension of Guerbet’s UNIK MRI solutions of contrast media, injectors, consumables, services and software. It will enable our customers to use a lower dose of gadolinium in their everyday clinical practice. Our ambition is to make this available to as many patients as soon as possible. This is a bold decision which will accelerate our ability to further develop Gadopiclesol, which will bring significant health benefits worldwide,” said CEO of Guerbet, David Hale

“Gadopiclesol represents real and valuable innovation in MRI, with a unique profile of stability and contrast enhancement properties that will allow a low dose to be effectively used in a large number of clinical settings and clinical indications,” said CEO of Bracco Imaging, Fulvio Renoldi Bracco. “We are excited about this strategic addition to Bracco Imaging’s MRI portfolio. Once approved, the addition of Gadopiclesol will expand our portfolio to include three different products that will help to shape the future of prevention and precision diagnostic imaging, in accordance with our global strategy.”

Guerbet will manufacture Gadopiclesol active ingredient and vials for Bracco Imaging for up to seven years. Following a technology transfer, both companies will have the ability to manufacture the product. The first marketing authorizations are anticipated in 2023, initially in the United States and the European Union (EU), with other geographies to follow.

About Gadopiclenol

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 clinical study data for this product to date. Details on Phase III 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

All these 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 Guerbet

At Guerbet, we build lasting relationships so that we enable people to live better. That is our purpose. We are a leader in medical imaging worldwide, offering a comprehensive range of pharmaceutical products, medical devices, and digital and AI solutions for diagnostic and interventional imaging. A pioneer in contrast media for 95 years, with more than 2,600 employees worldwide, we continuously innovate and devote 10% of our sales to research and development in 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, please visit www.guerbet.com.

About Bracco Imaging

Bracco Imaging S.p.A. ("Bracco Imaging"), part of the Bracco Group, is an innovative world leader delivering end-to-end products and solutions through its comprehensive portfolio across diagnostic imaging modalities. Headquartered in Milan, Italy, Bracco Imaging's purpose is to improve people's lives by shaping the future of prevention and precision diagnostic imaging. Bracco Imaging portfolio includes products and solutions for all key diagnostic imaging modalities: X-ray imaging, magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine. Bracco Imaging has approximately 3,600 employee and operates in more than 100 markets globally. Bracco Imaging has a well-skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. R&D activities are located in four centers based in Italy, Switzerland, the United Kingdom and the United States. Bracco Group global revenues were 1.4 billion Euros in 2020. To learn more about Bracco Imaging, visit www.braccoimaging.com.

Guerbet Forward-looking statements

Certain information contained in this press release does not reflect historical data but constitutes forward-looking statements. These forward-looking statements are based on estimates, forecasts, and assumptions, including but not limited to assumptions about the current and future strategy of the Guerbet Group ("Group") and the economic environment in which the Group operates.

They involve known and unknown risks, uncertainties, and other factors that may result in a significant difference between the Group's actual performance and results and those presented explicitly or implicitly by these forward-looking statements.

These forward-looking statements are valid only as of the date of this press release, and the Group expressly disclaims any obligation or commitment to publish an update or revision of the forward-looking statements contained in this press release to reflect changes in their underlying assumptions, events, conditions, or circumstances.

The forward-looking statements contained in this press release are for illustrative purposes only. Forward-looking statements and information are not guarantees of future performance and are subject to risks and uncertainties that are difficult to predict and are generally beyond the Group's control.

These risks and uncertainties include but are not limited to the uncertainties inherent in research and development, future clinical data and analyses (including after a marketing authorization is granted), decisions by regulatory authorities (such as the US Food and Drug Administration or the European Medicines Agency) regarding whether and when to approve any application for a drug, process, or biological product filed for any such product candidates, as well as their decisions regarding labeling and other factors that may affect the availability or commercial potential of such product candidates.

A detailed description of the risks and uncertainties related to the Group's activities can be found in chapter 4.8 "Management and risk factors" of the Group's Universal Registration Document filed with the AMF (French financial markets authority) under number D-20-0369 on April 28, 2020, available on the Group's website (www.guerbet.com).

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