Guerbet and Bracco Imaging Announce a Global Strategic Collaboration Agreement for Gadopiclenol on December 14, 2021

Companies will collaborate on manufacturing and research and development for future indications, and will commercialize Gadopiclenol, an investigational GBCA, independently under separate brands upon regulatory approval.

Gadopiclenol is an investigational macrocyclic GBCA contrast agent that has completed Phase III clinical studies and companies will prepare for regulatory submissions.

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

Guerbet, 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, announced that they have signed a global collaboration for Gadopiclenol, an investigational magnetic resonance imaging (MRI) contrast agent. This global collaboration will allow Guerbet and Bracco Imaging to commercialize Gadopiclenol independently under different brand names after regulatory approval. The companies will also collaborate on manufacturing, as well as research and development of the future indications for Gadopiclenol.

Guerbet announced results from two Phase III studies for the investigational macrocyclic gadolinium-based contrast agent, Gadopiclenol in March 2021. The results from the Phase III studies are available on the ClinicalTrials.gov database. Both Guerbet and Bracco Imaging each own valuable intellectual property relating to Gadopiclenol.

“Once approved, Gadopiclenol will be an excellent extension of Guerbet’s UNIK MRI solutions of contrast media, injectors, consumables, services and software. 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 Gadopiclenol,” said CEO of Guerbet, David Hale.

Upon regulatory approval, Guerbet will manufacture Gadopiclenol active ingredient and finished drug product in the vial presentation 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 is anticipated in 2023, initially in the United States and the European Union (EU), with other geographies to follow.

About Gadopiclenol

Gadopiclenol is an investigational macrocyclic gadolinium-based contrast agent 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 on 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, as planned in the United States and in the European Union (EU) early 2022.