GE Healthcare's Stress Agent Rapiscan Approved for Use in Stress Cardiac Magnetic Resonance Imaging

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- Already used in Single-Photon Emission Computed Tomography (SPECT) Myocardial Perfusion Imaging (MPI) for adult patients, Rapiscan is now approved for use in stress Cardiac Magnetic Resonance Imaging (CMR)
- Rapiscan, a pharmacological stress agent, is an alternative for patients who cannot exercise

Chalfont St Giles, UK – 14 February 2022 – GE Healthcare has announced that it has received approval from the European Medicines Agency (EMA) for additional imaging modalities for its stress agent Rapiscan (Regadenoson). Already an established pharmacological stress agent in SPECT MPI for adult patients, Rapiscan is now approved for use in Magnetic Resonance Imaging (MRI) as well as Computed Tomography (CT) and Positron Emission Tomography (PET).[1]

Rapiscan simulates the effects of exercise in the hearts of adult patients unable to exercise and is used to aid the diagnosis of coronary artery disease (CAD). The approval for additional imaging modalities will enable Rapiscan to be used with an MR contrast agent in stress CMR to assess the function and blood flow of the heart, enabling radiologists/cardiologists to perform a single stress/rest/MRI protocol.

Stress CMR has shown high diagnostic performance (sensitivity and specificity of 90% and above) compared to gold standard invasive imaging for coronary artery disease and is recommended for use in the 2019 European Society of Cardiology guidelines for the diagnosis and management of chronic coronary syndromes, along with other non-invasive diagnostic tests, such as stress SPECT MPI.[2]

Rapiscan can be used across a broad spectrum of patients as it does not require weight and age-based modifications or an infusion pump.

Dr Gianluca Pontone, Director of Cardiovascular Imaging Department, Monzino Cardiology Center at University of Milan said: “Our experience with Rapiscan in stress MR was very positive. We found it easy to use and very effective in helping to speed up the entire examination which was a key factor for us as was the high level of tolerance amongst patients.”

Dr Mark Hibberd, Chief Medical Officer at GE Healthcare Pharmaceutical Diagnostics, said: “Market authorisation of the additional imaging modalities for Rapiscan could make it easier for more patients, who are unable to exercise, to have this stress test and aid radiologists and cardiologists in making assessments.”

GE Healthcare has the commercial rights to promote Rapiscan excluding US, Mexico and Canada.

GE Healthcare Pharmaceutical Diagnostics imaging agents support three patient procedures every second worldwide across MRI, X-ray/CT and nuclear medicine imaging. Its portfolio of cardiology products aims to support diagnosis and monitoring throughout the cardiac care pathway and aid treatment decisions across multiple pathologies with products available for use in interventional angiography laboratories, and in CT, MRI, Echocardiography and SPECT imaging.

About GE Healthcare:

GE Healthcare is the $17.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 47,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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[1] Rapiscan (regadenoson) Summary of Product Characteristics (EN), GE Healthcare, December 2021.

[2] Danad I et al. Diagnostic performance of cardiac imaging methods to diagnose ischaemia-causing coronary artery disease when directly compared with fractional flow reserve as a reference standard: a meta-analysis. Eur Heart J 2017; 38(13): 991–8.

Knuuti J et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J 2020; 41(3): 407–77

Summary of Product Characteristics:

https://www.ema.europa.eu/en/documents/product-information/rapiscan-epar-product-information_en.pdf

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