

Bayer receives approval for Gadovist injection in Japan

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Bayer HealthCare received approval in Japan for Gadovist (gadobutrol) injection for use with magnetic resonance imaging (MRI).

Gadovist is the first high concentration/high relaxivity gadolinium-based contrast agent to be approved in Japan and is indicated for contrast-enhancement MRI in cranial, spinal, the body and extremities at a dose of 0.1 mL/kg body weight.

Bayer's Dr Christiane Pering, Chief Medical Officer (CMO) and Head of Innovation within [Bayer](#) HealthCare's Medical Care division, claims that the approval of Gadovist in Japan provides local radiologists with access to the first high concentration/high relaxivity gadolinium-based contrast agent.

Dr Pering also indicated that Gadovist has demonstrated efficacy in providing the potential of high quality images of the central nervous system and whole body for patients supporting effective diagnosis and disease management by their healthcare teams and ultimately enabling good patient care.

The approval of Gadovist in Japan was based on two key clinical studies involving patients from Japan.

A 223-patient Phase 3 open label study in Japan demonstrated superiority of gadobutrol-enhanced [MRI](#) of the central nervous system (CNS) compared to unenhanced MRI.