

Medexus Pharmaceuticals Inc

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Medexus gets Health Canada nod to market tumor imaging material Gleolan for neurosurgery

Medexus Pharmaceuticals Inc (CVE:MDP) (OTCQX:MEDXF) announced Thursday that it received a notice of compliance from Health Canada, granting the company approval to market its tumor imaging agent Gleolan in the country.

Gleolan, which is a 5-Aminolevulinic Acid (also known as 5-ALA), is essentially a dye that can make tumors and their small, finger-like projections more visible. After administration, areas within the tumor glow pink or red, and healthy brain tissue appears blue when exposed to a special blue light during surgery.

The agent has been approved for the visualization of malignant tissue during surgery in patients with Grades III or IV gliomas, a type of tumor that occurs in the brain and spinal cord.

READ: Medexus says its joint-disease drug added to public drug plan in Quebec and will enjoy insurance coverage

"We are very pleased to have received regulatory approval from Health Canada allowing Gleolan to be commercially available in Canada for use in fluorescence-guided brain cancer neurosurgery," CEO Ken d'Entremont said in a statement. "We are now able to access a much larger group of adult patients suffering from high-grade gliomas in Canada."

The company pointed to a Phase 3 study published in The Lancet Oncology Medical Journal, which showed that using Gleolan during brain tumour surgery nearly doubled the rate of achieving a complete resection of the tumour, which in turn has doubled the number of patients with no progression of their brain cancer six months after surgery

"The incidence of glioblastoma is 4 per 100,000 people in Canada and about 1,000 Canadians will be diagnosed with glioblastoma every year, according to the Brain Tumor Registry of Canada," said Susan Marshall, CEO of the Brain Tumor Foundation of Canada. "The feedback from the medical community has been extremely positive, and ... we expect Gleolan will be a tremendous asset for clinicians in addressing their significant medical need for enhanced tumor visualization during surgery."

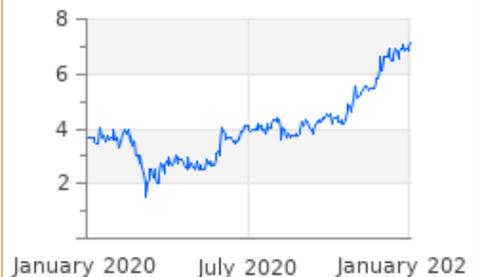
Ken d'Entremont thanked Medexus' partners at photonamic GmbH & Co for obtaining the full registration of Gleolan in Canada. The drug has already been approved in a plethora of other countries, including the US.

"Gleolan is already approved for use in more than 40 countries, including Germany, United States, United Kingdom, Japan, South Korea, Australia and New Zealand, and the approval in Canada marks another milestone in the global development of the drug," said photonamic CEO Ulrich Kosciessa. "We are delighted that Medexus has been able to successfully achieve an approval from Health Canada and that Gleolan will now be available for glioblastoma multiforme patients in Canada. More than 80,000 patients globally have already benefited from the use of Gleolan in

Price: 7.16

Market Cap: \$103.49 m

1 Year Share Price Graph



Share Information

Code: MDP

Listing: TSX-V

52 week	High	Low
	7.2	1.42

Sector: Pharma & Biotech

Website: www.medexusinc.com

Company Synopsis:

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform. The Company's vision is to provide the best healthcare products to healthcare professionals and patients, through our core values of Quality, Innovation, Customer Service and Teamwork. Medexus Pharmaceuticals is focused on the therapeutic areas of auto-immune disease, hematology and allergy.

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brain tumour resection."

Health Canada had previously granted Medexus authorization to distribute Gleolan in the county under the Special Access Programme, which provides healthcare practitioners with access to non-marketed drugs to treat patients with serious or life-threatening conditions when conventional therapies have failed, the company said.

In March, the quality business unit at Ontario Health recommended publicly funding Gleolan for guiding maximal surgical resection of high-grade gliomas, which was conditional on Health Canada approval of the technology. Medexus is awaiting final funding approval from the Ontario Ministry of Health.

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