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Medexus Demonstrates Cost-Effectiveness of Gleolan-Guided Surgery for High-Grade Glioma

ISPOR 2023 Presentation Shows 33% Lowered Costs with Gleolan Compared to Conventional White Light Surgery

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - May 9, 2023) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) today presented data demonstrating a 33% cost savings with Gleolan® (aminolevulinic acid HCl) oral solution, compared to conventional white light surgery, in US patients with high-grade glioma. The data were presented at ISPOR 2023, the annual meeting of the Professional Society for Health Economics and Outcomes Research (formerly known as the International Society for Pharmacoeconomics and Outcomes Research) in Boston, Mass.

"These latest data reinforce that the efficiencies from Gleolan clearly justify the costs in all appropriate patients in whom imaging complete resection, or ICR, is a goal of surgery," commented study investigator Andrew E. Sloan, MD, a neurosurgeon at Piedmont Healthcare in Atlanta, Ga.

Use of Gleolan has been associated with improved imaging complete resection (**ICR**). In the pivotal trial leading to its approval, the ICR rate for Gleolan-guided surgery was 64%, compared to 38% for conventional white light surgery.*

"Although Gleolan is additive to the cost of surgery, its use results in lower cost per ICR, and therefore is a more efficient use of resources in the surgical resection of high-grade glioma," said Mark Fosdal, DHSc, PA-C, Director of Scientific Communications at Medexus.

The study presented at ISPOR 2023 compared the cost per ICR with Gleolan-guided surgery (in conjunction with blue light) to that of conventional white light surgery in patients with high-grade glioma. In reviewing data from facilities representing 80% of all Gleolan utilization in the United States, the investigators calculated an average adjusted total cost savings per ICR of US$38,292 for Gleolan-guided surgery when compared to conventional white light surgery.

** Gleolan (aminolevulinic acid hydrochloride [ALA-HCl]) for oral solution prescribing information. US Food and Drug Administration (FDA). https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208630s000lbl.pdf. Accessed May 1, 2023.*

About Gleolan®

Gleolan is the first and only optical imaging agent approved by the US Food and Drug

Administration (**FDA**) for use in people with high-grade glioma (suspected World Health Organization [WHO] Grades III and IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery. Its active ingredient, aminolevulinic acid HCl (also known as 5-ALA), is a natural metabolite in the human body that is produced within the hemoglobin metabolic pathway.

When combined with white light and a blue filter, 5-ALA illuminates the brain tumor in a fluorescent pink color, allowing the neurosurgeon to see suspected malignant high-grade glioma tissue in real time. By providing the neurosurgeon with a better view of the surgical field, Gleolan facilitates a more precise and complete resection (removal) of the tumor.

NX Development Corp., the licensor of Medexus's commercialization rights to Gleolan in the United States, estimates that Gleolan has been used in more than 100,000 surgeries conducted in 42 countries worldwide. In pivotal studies in patients with suspected malignant high-grade glioma, use of Gleolan has been associated with decreased need for reoperation, no increased risk for long-term neurological complications, and reduced frequency and time to reintervention.**

Adverse reactions occurring in >1% of patients in the week following surgery were pyrexia, hypotension, nausea, and vomiting. For more information about Gleolan®, including additional important safety information and physician training information, see the Full Prescribing Information, which is available on the product's website at www.gleolan.com.

Gleolan®, as discussed in this news release, is approved by the FDA for sale and use in the United States only and is not intended for export outside the United States. Medexus makes no representation that Gleolan®, as discussed in this news release, is appropriate for, or authorized for sale to or use by, persons who are not located in the United States. Medexus holds exclusive commercialization rights to Gleolan® in the United States.

Gleolan®, as discussed in this news release, is a registered US trademark of photonamic GmbH & Co. KG. Solely for convenience, trademarks may appear without the "®" or similar symbols. Each such reference should be read as though it appears with the relevant symbol. Any such references are not intended to indicate, in any way, that the holder or holders of the relevant intellectual property rights will not assert those rights to the fullest extent under applicable law.

*** Stummer W, Pichlmeier U, Meinel T, Wiestler OD, Zanella F, Reulen H-J. Fluorescence-guided surgery with 5-aminolevulinic acid for resection of malignant glioma: a randomised controlled multicentre phase III trial. Lancet Oncol. 2006;7:392-401.*

About Medexus

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform and a growing portfolio of innovative and rare disease treatment solutions. Medexus's current focus is on the therapeutic areas of oncology, hematology, auto-immune diseases, and allergy. For more information about Medexus and its product portfolio, please see the company's corporate website at www.medexus.com and its filings on SEDAR at www.sedar.com.

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Forward-looking statements

Certain statements made in this news release contain forward-looking information within the meaning of applicable securities laws (**forward-looking statements**). The words "anticipates", "believes", "expects", "will", "plans", "potential", and similar words, phrases, or expressions are often intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words, phrases, or expressions. Specific forward-looking statements contained in this news release include, but are not limited to, statements regarding the potential healthcare economic and other benefits of Gleolan®. These statements are based on factors or assumptions that were applied in drawing a conclusion or making a forecast or projection, including assumptions based on historical trends, current conditions, and expected future developments, and, in particular, Medexus's interpretation and assessment of the data presented by Medexus as summarized in this news release. Since forward-looking statements relate to future events and conditions, by their very nature they require making assumptions and involve inherent risks and uncertainties. Medexus cautions that although it is believed that the assumptions are reasonable in the circumstances, these risks and uncertainties give rise to the possibility that actual results may differ materially from the expectations set out in the forward-looking statements. Material risk factors include, but are not limited to, those set out in Medexus's materials filed with the Canadian securities regulatory authorities from time to time, including Medexus's most recent annual information form and management's discussion and analysis. In addition, specific risks and uncertainties relevant to the content of this news release include, among other things, the uncertainties inherent in research initiatives (including the possibility of unfavorable new data and further analyses of existing data); the risk that data are subject to differing interpretations and assessments by regulatory authorities and/or other relevant third parties; and whether relevant third parties will be satisfied with the design and methodology of and results from the relevant study, which will depend on many factors, including determinations as to whether the product's benefits outweigh its known risks and determinations of the product's efficacy and cost-effectiveness in the context of a given facility (which varies by facility type). Accordingly, undue reliance should not be placed on these forward-looking statements, which are made only as of the date of this news release. Other than as specifically required by law, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

Uniform resource locators

Uniform resource locators, or website addresses, that appear in this news release are intended to be provided as inactive textual references only. Information contained on or accessible through these website addresses is not a part of this news release and is not incorporated by reference into this news release or any of Medexus's public filings.

Additional notes

The information in this news release is provided for informational purposes to investors in Medexus securities only, and is not intended to constitute promotion of any product nor any other activity that would violate any applicable law.

Medexus sponsored the publication referenced in this news release, and Medexus employees and paid consultants participated in the authoring and editing of the publication.



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