September 19, 2022

# Medexus Provides Update on Treosulfan NDA Resubmission and Provides Business Update

FDA requests further information from medac, continues to engage with treosulfan NDA

Medexus continues to focus on maintaining momentum and growth in its North American on-market portfolio, and is now recognizing 100% of Gleolan U.S. net sales as of September

Medexus to host live webcast on September 21, 2022 at 11:00 AM Eastern Time

TORONTO and CHICAGO, Sept. 19, 2022 (GLOBE NEWSWIRE) -- On Friday, September 16, Medexus Pharmaceuticals (**Medexus**) (TSX: MDP) (OTCQX: MEDXF) was informed by medac, licensor of Medexus's commercialization rights to treosulfan, that the U.S. Food and Drug Administration (**FDA**) has delivered to medac a second notice of incomplete response regarding medac's new drug application resubmission for treosulfan (**NDA**). The FDA's notice requests further supporting information from medac to complete medac's NDA resubmission but does not require submission of new clinical data. Medexus will provide an update to its shareholders and stakeholders once management knows whether the resubmission has been accepted and is better able to assess the impact of this delay.

"While we recognize that the FDA's response timeline has proven longer than anticipated, we are encouraged to see that the Agency remains engaged with medac to find a path towards resubmission," commented Ken d'Entremont, Chief Executive Officer of Medexus. "We continue to seek opportunities to collaborate with medac to the extent permitted by our license agreement in order to support medac in satisfying the FDA's requests and in upholding their responsibility for treosulfan regulatory matters. We are evaluating the potential impact of this delay, including on the timing of a commercial launch in the United States, and we are working with our regulatory and legal advisors to plan accordingly. We firmly believe that treosulfan would make a substantial difference for U.S. patients, as it has in Europe and Canada, and we remain optimistic about the prospect of a treosulfan approval in the United States."

Mr d'Entremont continued: "We remain focused on delivering strong revenue growth and improved overall performance in our current portfolio of products in both the United States and Canada. We were pleased to announce the strongest fiscal Q1 in our company's history by delivering a record US$23.0 million of revenue and improved operating performance. Overall, our monthly results so far suggest that we are heading towards another strong quarter."

**Gleolan U.S. sales update**

Medexus has now assumed full responsibility for commercializing Gleolan in the United States and has begun shipping Medexus-labeled product to customers across the country. Gleolan sales since March 2022, when Medexus acquired exclusive U.S. commercialization rights, have been in line with Medexus's expectations, and the company expects to continue that strong performance over the coming months. Medexus previously estimated that Gleolan had generated US$3 million to US$4 million in revenue in the last full quarter before Medexus acquired the exclusive right to commercialize Gleolan in the United States. During the now-completed transition period, Medexus had recognized a portion of total net sales in its revenue, net of an estimated royalty amount. September 2022 will be the first full month in which Medexus recognizes 100% of Gleolan net sales, on which Medexus will pay a tiered annual royalty.

Michael Adelman, General Manager—U.S. Operations, commented: "Completing this seamless transition to full commercialization responsibility is an important accomplishment for patients and customers. We and our partners have worked hard to ensure uninterrupted access to Gleolan and related support programs, and we remain focused on realizing Gleolan's full potential to improve neurosurgeons' ability to help high grade glioma patients across the United States and Canada, where Medexus launched Gleolan in February 2021. The institutional sales infrastructure we have built in our U.S. business will serve as a foundation for additional products with similar target accounts."

**Webcast information**

Medexus invites investors and other interested parties to view and listen to a live webcast at 11:00 am Eastern Time on Wednesday, September 21, 2022, with Adelaide Capital, Medexus's investor relations firm, to discuss the company's preparations for a commercial launch of treosulfan and other business updates.

To participate in the live webcast, please visit the Investors—News & Events section of Medexus's corporate website or register to join using the following link:

https://us02web.zoom.us/webinar/register/WN_T_6DJ9NoSj2XW3ikJdTLwQ

For more information about treosulfan and the NDA resubmission process, see Medexus's July 25, 2022 press release. For more information about Medexus's operating and financial results for the quarter ended June 30, 2022, see Medexus's August 8, 2022 press release. For more information about Gleolan, including a summary of Medexus's commercialization rights in the United States, see Medexus's March 1, 2022 press release. These and other Medexus press releases are available on the Investors—News & Events section of Medexus's corporate website.

**About Medexus**

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform and a portfolio of proven best-in-class products. Our current focus is on the therapeutic areas of hematology, auto-immune diseases, and allergy. We continue to build a highly differentiated company with a growing portfolio of innovative and high-value orphan and rare disease products that will underpin our growth for the next decade.

Our current leading products are IXINITY®, an intravenous recombinant factor IX therapeutic for use in patients 12 years of age or older with Hemophilia B (a hereditary bleeding disorder characterized by a deficiency of clotting factor IX in the blood, which is necessary to control bleeding); Rasuvo™ and Metoject®, a unique formulation of methotrexate (auto-pen and pre-filled syringe) designed to treat rheumatoid arthritis and other auto-immune diseases; and Rupall®, an innovative prescription allergy medication with a unique mode of action. We also hold exclusive US and Canadian rights to commercialize Gleolan™ (aminolevulinic acid hydrochloride or ALA HCl), an FDA-approved, orphan drug designated optical imaging agent currently indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

We have also licensed treosulfan, part of a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, for commercialization in the United States and Canada. Treosulfan was approved by Health Canada in June 2021 and is marketed in Canada as Trecondyv®. Treosulfan is currently the subject of a regulatory review process with the U.S. Food and Drug Administration.

Our mission is to provide the best healthcare products to healthcare professionals and patients. We strive to deliver on this mission by acting on our core values: Quality, Innovation, Customer Service, and Collaboration.

**Contacts**

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**Forward-Looking Statements**

Certain statements made in this press release contain, and statements made in the webcast discussed in this press release may 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 or expressions are often

intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Specific forward-looking statements contained in this news release include, but are not limited to, statements regarding Medexus's future financial or operating performance (including with respect to the expected results from sales of Gleolan in the United States), the timing and expected outcome of the FDA approval process for treosulfan and a related launch of the product in the United States, and Medexus's expectations regarding treosulfan's prospects if approved by the FDA. Specific forward-looking statements that may be contained in the webcast referred to in this press release may include, but are not limited to, information contained in statements regarding any of the following: Medexus's business strategy, outlook, and other expectations regarding financial or operational performance; anticipated trends and challenges in Medexus's business and the markets in which it operates, including the company's competitive position in and demographics of those markets; Medexus's expectations and plans regarding future growth and revenues and ability to pay dividends and distributions; Medexus's expectations regarding the business strategies of its competitors; Medexus's expectations regarding availability of funds from operations, cash flow generation, and capital allocation, and anticipated cash needs, capital requirements, and needs for additional financing; Medexus's ability to secure and fund commercialization rights to promising products and the performance of those products against expectations; the ability of Medexus and its business partners to secure regulatory approvals from the FDA, Health Canada, and other agencies when required; and the potential ongoing impact of the Covid-19 pandemic (including any variants) and Medexus's response, including any balance-sheet and cost management strategies and any benefits from those strategies. 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. 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 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; future capital requirements and dilution; intellectual property protection and infringement risks; competition (including potential for generic competition); reliance on key management personnel; Medexus's ability to implement its business plan; Medexus's ability to leverage its U.S. and Canadian infrastructure to promote additional growth; regulatory approval by relevant health authorities, including the FDA; product reimbursement by third party payers; litigation or expiry with respect to patents or other intellectual property rights; litigation risk; stock price volatility; government regulation; and potential third party claims. Given these risks, undue reliance should not be placed on these forward-looking statements, which are made only as of the date hereof. Other than as specifically required by law, Medexus undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.




Source: Medexus Pharmaceuticals Inc