January 12, 2023

# Medexus Expects Record Revenue for Fiscal Q3 2023 and Provides Business Update

## Quarterly revenue expected to exceed US$28.5 million for quarter ended December 31, 2022, an all-time record

TORONTO and CHICAGO, Jan. 12, 2023 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals (**Medexus**) (TSX: MDP) (OTCQX: MEDXF) is pleased to announce preliminary estimates of the company's revenue results for the fiscal quarter ended December 31, 2022 (the company's fiscal Q3 2023) and provide additional business updates to shareholders and other stakeholders. All dollar amounts in this press release are in US dollars unless specified otherwise.

**Preliminary revenue estimates for fiscal Q3 2023**

Medexus expects to deliver total revenue between $28.5 million and $29.0 million in fiscal Q3 2023. This will represent another record quarter of revenue for Medexus, and a year-over-year increase of at least 34% and a quarter-over-quarter increase of at least 3%.

Primary drivers for the most recent quarter's improved revenue performance were increases in net sales across Medexus's portfolio. Medexus expects key highlights to include the following –

- **IXINITY**: Positive trend in sales, reflecting new patient conversions on top of a stable, existing base of patients.
- **Rasuvo**: Continued strong performance and maintenance of the product's leading position in the moderately-growing US branded methotrexate market with a limited sales force allocation.
- **Rupall**: Continued strong demand exhibiting typical seasonality as compared to fiscal Q2 2023, reflecting successful execution of the company's sales and marketing initiatives and sustaining the product's strong performance over the five years since launch.
- **Gleolan**: Continued positive trend in US sales, positioning Medexus to successfully execute its post-transition commercial plan including new sales and marketing initiatives.

The expected results discussed in this press release are preliminary estimates, as Medexus's financial closing procedures remain subject to completion, and have not been reviewed by the company's auditors. Accordingly, the final reported results may diverge from these estimates.

**Updates on treosulfan and current business strategy**

Since Medexus's last update in November 2022, medac, as the party responsible for regulatory matters under Medexus's license agreement for treosulfan, has continued to engage with the US Food and Drug Administration (**FDA**) regarding medac's resubmission of its new drug application for treosulfan (**NDA**). medac's engagement has primarily focused on establishing the most appropriate approach to addressing the remaining items noted in FDA's second notice of incomplete response delivered to medac in September 2022. The FDA continues to seek supporting information from medac relating to the pivotal phase 3 clinical trial of treosulfan conducted by medac.

Based on Medexus's assessment of the FDA's feedback and discussions with medac, Medexus now expects that it would take medac up to a year or more to collect and submit the information requested by the FDA. The FDA would then evaluate the completeness of the available information submitted and medac's response and, if considered to be complete, then proceed to review medac's NDA resubmission. The FDA has made clear in its communications to medac that FDA review will not progress further unless and until medac collects this supporting information and otherwise responds to the FDA's remaining requests.

Medexus believes that treosulfan would make a substantial difference for US patients and therefore continues to urge medac to take the steps necessary to respond to the FDA's requests in a timely and complete fashion and fulfill medac's obligations under the terms of the treosulfan license agreement to pursue all commercially viable paths to completing the NDA resubmission. In the meantime, Medexus remains focused on commercializing the company's current product portfolio and seeking out additional complementary product opportunities that leverage the company's existing commercial platform. Medexus will continue seeking to deliver strong financial results for the company and its investors by pursuing this strategy in the near term.

**About Medexus**

Medexus is a leader in innovative and 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; Rupall®, an innovative prescription allergy medication with a unique mode of action; and 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 US 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 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 in this news release include, but are not limited to, statements regarding: Medexus's expected revenue for fiscal Q3 2023, business strategy, outlook, future growth plans, and other expectations regarding financial or operational performance; and the occurrence, timing, and expected outcome of the FDA review process for treosulfan and any related collection and submission of information by medac. 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, 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. Given these risks, 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.


Source: Medexus Pharmaceuticals Inc