August 16, 2021

Medexus Pharmaceuticals Reports Financial and Operational Results for First Quarter Fiscal 2022

Continued strength in unit demand across key product lines

Rupall unit demand growth of 44% for the 12 months ending June 30, 2021

Completion of enrollment for IXINITY® Phase 4 clinical pediatric trials

Management to host conference call at 8:00 AM Eastern Time on August 17th, 2021

TORONTO and CHICAGO, Aug. 16, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. ("**Medexus**" or the "**Company**") (TSX: MDP) (OTCQX: MEDXF) today announced its financial results and provided a business update for the three-month period ended June 30, 2021. All dollar amounts below are in United States dollars unless specified otherwise.

First Quarter Fiscal 2022 Financial Highlights*:

- Revenue of $17.3 million compared to $20 million for Q1 of fiscal 2021. The decrease in net sales was due to a temporary decline in ex-factory sales of IXINITY®, as pharmacy and wholesale customers continued to work through inventory on hand. Despite the decreased sales, patient unit demand for IXINITY® increased 25.3% compared to the corresponding period in the prior year, to 7.6 million IUs, which reflects the Company's successful commercial efforts. These efforts are expected to be realized in strong ex-factory sales and improved gross margin, once the inventory on hand is reduced to normal levels, in the coming quarters.
- Adjusted EBITDA* decreased to $(4.9) million compared to $3.6 million for the same period last year, due primarily to the decrease in Net Sales, the impact of a manufacturing expense related to IXINITY®, an increase in Research & Development Costs over the comparative period due to the ramp up of the IXINITY® pediatric trial, and the investments the Company made related to plans for the commercialization of treosulfan.
- Cash used by operating activities was $6.8 million, compared to cash provided by operating activities of $3.0 million for the same period last year. $5 million of the cash used was a milestone payment to medac for the treosulfan license. There are no additional milestone payments for that license until approval.
- Net loss was $6.6 million compared to $3.4 million for the same period last year.
- Adjusted Net Loss* (which adjusts for such unrealized losses (or gains) on the fair value of derivatives) was $9.8 million compared to $0.8 million for the same period last year.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "We continued to see pressure on IXINITY® ex-factory sales this past quarter, due to the high level of product in the distribution channel. We believe that we are making progress in normalizing the distribution channel and are highly encouraged by growing demand. Specifically, unit demand for IXINITY® increased 25% over the corresponding quarter in the prior year, which follows a 15% increase in demand for the twelve months ended March 31, 2021. We are confident that we will be able capitalize on this growth to both increase revenue and improve our margins as we implement supply chain improvements."

"Looking towards the balance of the year, the US approval for treosulfan will remain a major priority. The recent Complete Response Letter was not expected, however, we remain confident in the data that supports the use in patients with Acute Myeloid Leukemia and Myelodysplastic Syndrome. To our knowledge, no other agency has refused approval of treosulfan, with Health Canada most recently providing our Company with a Notice of Compliance, and approving its commercialization. Beyond treosulfan, we see tremendous opportunity across the rest of our product portfolio. We have historically generated very strong organic growth and we anticipate this will continue. We are also looking at a number of exciting new opportunities and are determined to continue our growth trajectory."

"Finally, we were pleased to announce the appointment of Marcel Konrad last month as our new CFO, who is a vital addition to our team as our focus increasingly turns to the US market. Moreover, we continue to maintain strict financial discipline and believe we have built a highly scalable business model that will generate significant value for our shareholders in the months and years ahead."

Operational Highlights:

Operational highlights for the three-month period ended June 30, 2021, or subsequent to the period end, include:

- **Treosulfan US Licensing Agreement:** During the year ended March 31, 2021, the Company entered into an exclusive license to commercialize treosulfan in the United States. Treosulfan is an innovative, orphan-designated agent developed for use as part of a conditioning treatment, in combination with fludarabine as a preparative regimen, for patients undergoing allogeneic hematopoietic stem cell transplantation ("allo-HSCT"). On August 2, 2021 the Company received notice from medac, Medexus's licensor for treosulfan, that is had received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration ("FDA") with respect to the New Drug Application ("NDA") for use of treosulfan in the United States. Via the CRL, the FDA has determined that it cannot approve the NDA in its present form. The FDA has however provided recommendations for how to address what they see as the outstanding issues, primarily around the provision of additional clinical and statistical data and analyses pertaining to the primary endpoint of the completed pivotal Phase III study. The steps associated with addressing these recommendations are already covered by medac's existing development plan for treosulfan, which medac is contractually responsible to execute and fund. The Company, together with medac, plans to move forward with the FDA, to meet the agency's requests. It is the Company's belief that the CRL provides a path to review and approval that does not require additional clinical studies, provided medac can satisfy the FDA's data

requirements and post marketing commitments, which the Company is hopeful can be done with already available data from the existing completed Phase III study and the current development plan.

- **Treosulfan Canada:** On June 28, 2021, the Company received a Notice of Compliance from Health Canada to commercialize treosulfan in Canada under the tradename Trecondyv® and on July 12, 2021, the Company entered into an exclusive license with medac to commercialize treosulfan in Canada. Previously, the Company had been distributing treosulfan in Canada only under the Special Access Program pursuant to the authorization received in March of 2019.
- **Rupall™:** Unit demand growth reached 44.4% for the trailing twelve-months ended June 30, 2021, which reflects further acceleration compared to the unit demand growth of 35.7% seen for trailing twelve-months ended March 31, 2021.[1] This due to a strong allergy season across Canada, and further market share gain by the brand. Rupall™ is one of the fastest growing anti-histamines in the Canadian prescription market[2].
- **IXINITY®**: On August 12, 2021, the Company announced the completion of enrollment for the Phase 4 clinical trial to evaluate the safety and efficacy of IXINITY® in previously treated patients under 12 years of age with hemophilia B. Medexus expects the trial to be completed in June of 2022. Once completed, this study may support a significant expansion of the indicated patient population for IXINITY® as approximately 1 in 3 patients treated for hemophilia B in the United States are 12 years of age or younger.
- **Graduation to Toronto Stock Exchange:** On June 17, 2021, the Company's common shares, which had previously been listed for trading on the TSX Venture exchange, began trading on the TSX.
- **Appointment of New CFO:** On July 19, 2021, the Company introduced Marcel Konrad as the new CFO replacing Roland Boivin. Marcel brings broad understanding of the healthcare market, having worked in companies large and small, ranging from Novartis to most recently, CareDx. The company believes that his experience will be instrumental to its continued growth in the future. Roland Boivin will continue in the company for a period of 3 months to help ensure a smooth transition.

Operating and Financial Results Summary for the Three Months Ended June 30, 2021:

Total revenue reached $17.3 million for the three-month period ended June 30, 2021, compared to revenue of $20 million for the three-month period ended June 30, 2020, mainly due to a drop in IXINITY® net sales. While patient unit demand for IXINITY® continued to grow, net sales were lower as pharmacy and wholesale customers worked through inventory on hand.

Gross profit reached $6.9 million for the three-month period ended June 30, 2021, compared to gross profit of $10.9 million for the three-month period ended June 30, 2020. Gross profit for the three-month period ended June 30, 2021, has been impacted by a $2.5 million increase in cost of goods sold, related to a manufacturing expense for IXINITY®.

The gross margin was 40.1% for the three-month period ended June 30, 2021, compared to 54.5% for the three-month period ended June 30, 2020. The lower gross margins for the current period were a direct result of the manufacturing expense for IXINITY®. Normalized for this $2.5 million impact, the gross margin for the three-month period ended June 30,

2021, would have been 54.6%.

Operating loss for the three-month period ended June 30, 2021, was $7.2 million compared to an operating income of $1.2 million for the three-month period ended June 30, 2020.

Adjusted EBITDA was $(4.9) million for the three-month period ended June 30, 2021, compared to Adjusted EBITDA of $3.6 million for the three-months period ended June 30, 2020.

Net loss was $6.6 million compared to $3.4 million for the same period last year. This included a non-cash unrealized gain of $3.2 million in the current period on the fair value of the embedded derivatives in the Company's convertible debentures, which was driven by a decrease in the Company's share price at the end of the applicable periods.

The Company's financial statements and management discussion and analysis ("MD&A") for the period ended June 30, 2021 are available on our corporate website at www.medexus.com and in our corporate filings on SEDAR at www.sedar.com.

** Refer to "Non-IFRS Financial Measures" at the end of this press release.*

Conference Call Details

Medexus will host a conference call at 8:00 AM Eastern Time on Tuesday, August 17, 2021 to discuss the Company's financial results for the fiscal 2022 first quarter ended June 30, 2021, as well as the Company's corporate progress and other developments.

The conference call will be available via telephone by dialing toll free 844-602-0380 for Canadian and U.S. callers or +1 862-298-0970 for international callers. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2010/42339 or on the Company's Investor Events section of the website: https://www.medexus.com/en_US/investors/news-events.

A webcast replay will be available on the Company's Investor Events section of the website (https://www.medexus.com/en_US/investors/news-events) through Wednesday, August 17, 2022. A telephone replay of the call will be available approximately one hour following the call, through Tuesday, August 24, 2021 and can be accessed by dialing 877-481-4010 for Canadian and U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 42339.

[1]*Source: IQVIA CDH units – Drugstores and hospitals purchases*
[2]*Source: IQVIA CDH units – Drugstores and hospitals purchases, MAT June 2021*

About Medexus

Medexus is a leader in innovative rare disease treatment solutions with a strong North American commercial platform. From a foundation of proven best in class products we are building a highly differentiated company with a portfolio of innovative and high value orphan and rare disease products that will underpin our growth for the next decade. 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 hematology, auto-immune disease, and allergy. The Company's leading products are: Rasuvo™ and Metoject®, a unique formulation of methotrexate (auto-pen and pre-filled syringe) designed to treat rheumatoid arthritis and other auto-immune diseases; 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; and Rupall®, an innovative prescription allergy medication with a unique mode of action. The Company has also licensed treosulfan, a preparative regimen for allogeneic hematopoietic stem cell transplantation to be used in combination with fludarabine, from medac GmbH for Canada and the United States.

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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" and similar 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 with respect to the implementation of supply chain improvements and the Company's ability to benefit from the same; future expectations regarding the Company's growth trajectory and future revenues; expectations regarding approval by the FDA for treosulfan and the ability to satisfy the FDA's requirements without the need additional clinical studies. 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. The Company 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 the Company's materials filed with the Canadian securities regulatory authorities from time to time, including the Company'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; the Company's ability to implement its business plan; the Company's ability to leverage its United States and Canadian infrastructure to promote additional growth; regulatory approval by the health authorities; product reimbursement by third party payers; patent litigation or patent expiry; 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 apply only as of the date hereof. Other than as specifically required by law, the Company undertakes no obligation to update any forward-looking statements to reflect new information, subsequent or otherwise.

Non-IFRS Financial Measures

This press release uses the terms "Adjusted Net Income (Loss)" and "Adjusted EBITDA" which are non-IFRS financial measures, which do not have any standardized meaning prescribed by IFRS and are therefore unlikely to be comparable to similar measures presented by other companies. Rather, these measures are provided as additional information to complement those IFRS measures by providing further understanding of the Company's results of operations from management's perspective. Accordingly, they should not be considered in isolation nor as a substitute for analysis of the Company's financial information reported under IFRS. In particular, management uses Adjusted Net Income (Loss) and Adjusted EBITDA as measures of the Company's performance. The Company defines Adjusted Net Income (Loss) as net income (loss) before unrealized loss (gain) on fair value of derivatives. The Company defines Adjusted EBITDA as earnings before financing and special transaction costs (including, for greater certainty, fees related to the acquisitions and related financings), interest expenses, income taxes, interest income, depreciation of property and equipment, amortization of intangible assets, non-cash share-based compensation, income from sale of assets, gain or loss on the convertible debenture embedded derivative, foreign exchange gains or losses, termination benefits, and impairment of intangible assets. The Company considers Adjusted Net Income (Loss) and Adjusted EBITDA as key metrics in assessing business performance and considers Adjusted EBITDA to be an important measure of operating performance and cash flow, providing useful information to investors and analysts. These non-IFRS measures are not intended to represent cash provided by operating activities, net earnings or other measures of financial performance calculated in accordance with IFRS. Additional information relating to the use of these non-IFRS measures, including the reconciliation of each of Adjusted Net Income (Loss) and Adjusted EBITDA to Net Income (Loss), can be found in our MD&A, which is available through the SEDAR website (www.sedar.com).



Source: Medexus Pharmaceuticals Inc