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Medexus Strengthens Medical Affairs Team in Preparation for Planned Treosulfan Launch

TORONTO, CHICAGO and MONTREAL, June 10, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "**Company**" or **"Medexus**") (TSXV: MDP) (OTCQX: MEDXF) (Frankfurt: P731) today announced that it has expanded its medical affairs team in preparation for the planned launch of treosulfan, a bifunctional alkylating agent, in the United States.

Treosulfan is an innovative, orphan-designated agent developed for use as part of a conditioning treatment for patients undergoing allogeneic hematopoietic stem cell transplantation ("**allo-HSCT**"). With more than 100 publications supporting its safety and efficacy, management believes treosulfan is ideally positioned to become the new standard of care in the U.S. As such, pro-actively putting in place the right people and resources ahead of the scheduled Prescription Drug User Fee Act ("**PDUFA**") date, which is set for August 2021, is critical to both the successful and timely launch of this innovative product for the benefit of patients and maximizing the value of the seven and a half years of exclusivity the Company expects to receive upon FDA approval. The hires announced today of Keith Steward, MD, MBA, Senior Vice President of Medical Affairs, J. Lynn Bass, B.S, PharmD, Senior Director of Medical Sciences and Mark Fosdal, DHSc, PA-C, Director, Scientific Communications are all part of that pro-active plan.

Ken d'Entremont, CEO, commented, "We expect the launch of treosulfan to be a major milestone for Medexus as it is a truly innovative, best-in-class product that addresses a substantial and underserved market. Before it was genericized in 2016, the current market leading product reached peak annual sales of U.S.$126 million in the United States despite lacking indications for use in patients with AML or MDS.[1] Treosulfan is expected to be approved for these indications. For treosulfan, the confirmatory interim analysis of the Phase III Study achieved two-year event-free survival of 64.0% (95% CI 56.0–70.9). This was a marked and statistically significant improvement compared to the busulfan group survival rate of 50.4% (95% CI 42.8–57.5) (HR 0.65 [95% CI 0.47–0.90]); p=0.0000164 (adjusted p-value for testing non-inferiority of treosulfan compared to busulfan)[2]. To support our expected launch later in 2021, we have put together an exceptional team in all areas of the business. The newly hired Medical Affairs leadership team will immediately be focused on building a field-based Medical Science Liaison team, kicking off our data generation and communication plans, and establishing Medexus as a truly vested partner through extensive outreach with key opinion leaders at transplant Centers of Excellence across the country."

Keith Steward, MD, MBA, will lead the team as Senior Vice President of Medical Affairs. Mr. Steward has over 20 years of global pharmaceutical and biotech industry experience. Most recently, he served as Global Head of Medical Affairs at QED Therapeutics. He has held

several executive and senior level positions throughout his career at companies like EMD (Merck KGaA), Pharmacia and Sanofi-Aventis as well as President/GM for a CME accredited global medical education company. Mr. Steward has significant NDA filing and launch experience for several first-in-class drugs across various therapeutic areas, including oncology and other rare diseases. He also has extensive experience leading multi-departmental organizations focusing on clinical development and medical affairs across multiple therapeutic areas. Dr. Steward received his Medical Degree from Eastern Virginia Medical School in Norfolk, Virginia and completed a Masters in Health Administration from the University of Tennessee, Knoxville.

J. Lynn Bass, B.S, PharmD, joins Medexus as Senior Director of Medical Sciences with over 20 years of experience in field Medical Affairs leadership roles at various pharmaceutical companies, including Eli Lilly, Amgen, Baxter, and Jazz, where her roles included building and managing field medical teams. Her industry career has spanned several therapeutic areas, including Hematology and Stem Cell Transplantation. Most recently Lynn served as Senior Director and Head of Medical Science Liaisons at Mesoblast. Lynn previously worked at Kaiser Permanente and the Department of Defense's Pharmacoeconomic Center as a Clinical Pharmacist following a career as a clinical microbiologist. Dr. Bass serves as the Chairperson for the global MSL community of the Drug Information Association (DIA) and is a frequent invited speaker on MSL and Medical Affairs related topics.

Mark Fosdal, DHSc, PA-C was hired as Director, Scientific Communications. Dr. Fosdal began his clinical career working as a Physician Assistant at the Fred Hutchinson Cancer Research Center in Seattle while caring for patients undergoing both autologous and allogeneic stem cell transplants. He also participated in running their clinical trials, training visiting physicians, fellows and oncoming staff in managing this population of patients. He has exceptional experience working with indications within hematological malignancies as an MSL and more recently as a Disease Area Lead at Pharmacyclics where he led medical affairs in the cross functional effort in launching of Imbruvica as the first approved drug in treating chronic graft versus host disease. Most recently, Mark served as Executive Medical Science Liaison at Atara Biotherapeutics. Mark received his doctorate in Health Science from Nova Southeastern University and Masters in Hematology/Oncology from the University of Nebraska Medical Center. He also has a bachelor's degree as a Physician Assistant.

With an excellent medical affairs team in place combined with an outstanding commercial infrastructure in the United States, Medexus believes that it is solidly positioning itself to address the underserved allo-HSCT market.

[1] *Symphony Health PHAST Data 2020*

[2] *Beelen, DW et al., Final Results of a Prospective Randomized Multicenter Phase III Trial Comparing Treosulfan / Fludarabine to Reduced Intensity Conditioning with Busulfan / Fludarabine Prior to Allogeneic Hematopoietic Stem Cell Transplantation in Elderly or Comorbid Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome. Blood. 2017;130 (Suppl 1):521*

About Medexus

Medexus is a leading innovative and rare disease company 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 auto-immune disease, hematology, 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.

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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 expected timing of the PDUFA date for treosulfan, the expected years of exclusivity for the indication of treosulfan, the

expected receipt of regulatory approvals, the potential for treosulfan to become the new standard of care in the U.S., the ability of the newly-hired Medical Affairs leadership team to effectively implement the Company's plans and strategies, the potential market size for treosulfan, and Medexus' positioning to address the underserved allo-HSCT market. 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, as well as assumptions regarding the receipt of regulatory approvals and the size of the available market.

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 but are not limited to risks related to 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 existing infrastructure to promote additional growth, patent litigation or patent expiry; litigation risk; stock price volatility; government regulation; potential third party claims, and such other risks as are 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. 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.

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