November 16, 2020

Medexus Reaches 50% Enrollment in IXINITY® Phase 4 Clinical Trial Targeting Label Expansion for Pediatric Hemophilia B Patients

TORONTO, CHICAGO and MONTREAL, Nov. 16, 2020 (GLOBE NEWSWIRE) -- **Medexus Pharmaceuticals Inc. (the "Company" or "Medexus") (TSXV: MDP, OTCQX: MEDXF)** today announced it has reached the 50% enrollment target in its Phase 4 clinical trial investigating IXINITY® as a prophylactic treatment for pediatric patients under 12 years of age with hemophilia B, a hereditary bleeding disorder characterized by a deficiency of clotting factor IX. IXINITY is an FDA approved intravenous recombinant factor IX therapeutic for use in patients 12 years of age or older with hemophilia B.

On February 28, 2020, Medexus announced the acquisition of the worldwide rights to the commercial hematology asset, IXINITY®, from Aptevo Therapeutics, Inc. (NASDAQ: APVO). In January 2020, Aptevo had already commenced dosing patients in a Phase 4 clinical trial to evaluate the safety and efficacy of IXINITY® in previously treated patients under 12 years of age with hemophilia B. Once completed, this study may support a significant expansion of the indicated patient population for IXINITY®. According to the World Federation of Hemophilia 'Report on the Annual Global Survey 2017,' approximately 1 in 3 patients treated for hemophilia B in the U.S. are 12 years of age or younger.

Khaled Mohamed, Director of Regulatory Affairs for Medexus, commented, "We are encouraged by the steady progress of our IXINITY® Phase 4 pediatric clinical trial, as we have now reached the 50% enrollment target and are on track to complete enrollment by the second calendar quarter of 2021. We look forward to completing this current study, which we are hopeful will allow us to expand the product label to include the U.S. pediatric population below 12 years of age."

Ken d'Entremont, Chief Executive Officer of Medexus, continued, "The hemophilia B market in the U.S. alone is estimated to be in excess of USD $1 billion. Since the pediatric segment is estimated to represent one-third of the hemophilia B population, a label expansion represents a possible expansion of the potential for IXINITY®. Most importantly, we look forward to providing this important, additional therapy option to the pediatric population. Previously reported and pooled data from Phase 3 clinical trials demonstrated IXINITY® to be safe and well tolerated in preventing and controlling bleeding episodes in previously treated children under the age of 12 with hemophilia B. We remain determined to advance our IXINITY® Phase 4 pediatric clinical trial and look forward to providing further updates as we achieve key milestones."

Medexus intends to also pursue out-license partners for IXINITY® in markets outside of

Canada and the United States. The company will provide further updates as they develop.

About Medexus Pharmaceuticals Inc.
Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform. 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 potential expansion of the indicated patient population for IXINITY® and possible expansion of potential for IXINITY®, the timing for completion of enrollment in the Phase 4 pediatric clinical trial and the intent to pursue out-license partners for IXINITY®. 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 most recent MD&A; 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, including with respect to the infrastructure of Medexus Inc. and Medac Pharma, Inc. and the potential benefits the Company expects to derive therefrom; regulatory approval by the Canadian 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.

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