August 12, 2021

Medexus Completes Enrollment in Phase 4 Clinical Trial of IXINITY® Targeting Label Expansion for Pediatric Hemophilia B Patients

TORONTO and CHICAGO, Aug. 12, 2021 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "**Company**" or "**Medexus**") (TSX: MDP) (OTCQX: MEDXF) today announced that is has completed enrollment in its Phase 4 Clinical Trial of IXINITY®, targeting label expansion for pediatric hemophilia B patients.

The Trial is 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 currently an FDA approved intravenous recombinant factor IX therapeutic for use in patients 12 years of age or older with hemophilia B.

Medexus has now enrolled its last patient in this Phase 4 Clinical Trial, with the trial expected to be complete in June 2022. On completion, the Company believes this study may support an 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 pleased to have enrolled our final patient for the IXINITY® Phase 4 pediatric clinical trial. We are hopeful that this study will allow us to expand the product label to include the U.S. pediatric population below 12 years of age. We believe this could prove to be a vital, additional therapy option to the pediatric population and look forward to submitting the full data set to FDA by end of 2022."

Ken d'Entremont, Chief Executive Officer of Medexus, noted, "The hemophilia B market in the U.S. alone is estimated to be in excess of USD $1 billion[1]. A label expansion inclusive of the pediatric market represents a significant market opportunity for IXINITY®. 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 treated children under the age of 12 with hemophilia B. If approved, we expect to be well positioned to commercialize quickly with the infrastructure we already have in place for the adult market. Additionally, we expect our research and development expenses will come down once the final dose has been administered."

Medexus intends to continue to pursue out-license partners for IXINITY® in markets outside of Canada and the United States. The Company will provide further updates as it achieves

key milestones.

[1]The Marketing Research Bureau Inc., "The Factor IX Market in theUnited States 2018", extracted from "The Plasma Proteins Market in the United States 2018", customized report for Aptevo BioTherapeutics, LLC, August 2019

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 in the United States.

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Forward looking and other cautionary 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 timing for completion of the Phase 4 trial and submission of the related data set to the FDA, the possibility of an FDA approval for a label expansion and ability of commercialize thereafter, and the anticipated decrease in research and development expenses. 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.



Source: Medexus Pharmaceuticals Inc