June 15, 2023

FDA Accepts for Review Medexus's IXINITY Supplemental Biological License Application for Pediatric Patients

Expanded indication would cover patients 12 years of age or younger, a population that comprises approximately one in three patients treated for hemophilia B in the United States

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - June 15, 2023) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) today announced that the US Food and Drug Administration (**FDA**) recently accepted for review Medexus's supplemental Biological License Application (**sBLA**) for IXINITY® [coagulation factor IX (recombinant)] for the on-demand, prophylactic, and perioperative treatment of pediatric patients under 12 years of age with hemophilia B - a hereditary bleeding disorder characterized by a deficiency of clotting factor IX in the blood. IXINITY®, an intravenous recombinant factor IX therapeutic, is currently approved for use in patients 12 years of age or older with hemophilia B.

"Approximately one third of patients treated for hemophilia B in the United States are children 13 years of age and under," said Ken d'Entremont, Chief Executive Officer of Medexus. "Risk of bleeding events can severely limit these children's daily activities. The FDA's commitment to review our sBLA brings us a step closer to making IXINITY® a viable factor IX treatment option for this important population."

* Source: World Federation of Hemophilia Report on the Annual Global Survey 2021; www1.wfh.org/publications/files/pdf-2324.pdf (accessed June 13, 2023).

About IXINITY®

IXINITY® [coagulation factor IX (recombinant)] Lyophilized Powder for Solution for Intravenous Injection is a coagulation factor IX (recombinant) indicated in adults and children ≥12 years of age with hemophilia B for on-demand treatment and control of bleeding episodes, perioperative management, and for routine prophylaxis to reduce the frequency of bleeding episodes.

The most common adverse reaction observed in >2% of patients in clinical trials was headache. For more information about IXINITY®, including important safety information, see the full prescribing information, which is available on the product's website at: www.ixinity.com.

IXINITY® is approved by the FDA for sale and use in the United States only and is not intended for export outside the United States. Medexus makes no representation that IXINITY® is appropriate for, or authorized for sale to or use by, persons who are not located in the United States.

About hemophilia B

Hemophilia B is a genetic bleeding disorder caused by a deficiency of coagulation factor IX, a protein needed to produce blood clots to stop bleeding. The clinical spectrum may include spontaneous or trauma-induced bleeding into joints, muscles, and soft tissues, resulting in joint damage, reduction in mobility, and severe arthritis, all of which negatively impact health-related quality of life. The primary aim of care is to prevent and treat bleeding by replacing the deficient clotting factor.

About Medexus

Medexus is a leading specialty pharmaceutical company with a strong North American commercial platform and a growing portfolio of innovative and rare disease treatment solutions. Medexus's current focus is on the therapeutic areas of oncology, hematology, rheumatology, auto-immune diseases, allergy, and dermatology. For more information about Medexus and its product portfolio, please see the company's corporate website at www.medexus.com and its filings on SEDAR at www.sedar.com.

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Forward-looking statements

Certain statements made in this news 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 contained in this news release include, but are not limited to, statements regarding the potential benefits of IXINITY®, the occurrence, timing, and expected outcome of the FDA review process for the sBLA for IXINITY® discussed in this news release, and expectations regarding the product's prospects if approved by the FDA. 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. In addition, specific risks and uncertainties relevant to the content of this news release include, among other things, the uncertainties inherent in research initiatives (including the possibility of unfavorable new data and further analyses of existing data); the risk that data are subject to differing interpretations and assessments by regulatory authorities and/or other relevant third parties; and whether regulatory authorities and/or other relevant third parties will be satisfied with the design and methodology of and results from the relevant study, which will depend on many factors, including determinations as to whether the product's benefits outweigh its known risks. Accordingly, 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.

Additional notes

IXINITY®, as discussed in this news release, is a trademark of Medexus. Solely for convenience, trademarks may appear without the "™", "®", or similar symbols. Each such reference should be read as though it appears with the relevant symbol. Any such references are not intended to indicate, in any way, that the holder or holders of the relevant intellectual property rights will not assert those rights to the fullest extent under applicable law.

The information in this news release is provided for informational purposes to investors in Medexus securities.

Uniform resource locators, or website addresses, that appear in this news release are intended to be provided as inactive textual references only. Information contained on or accessible through these website addresses is not a part of this news release and is not incorporated by reference into this news release or any of Medexus's public filings.

To view the source version of this press release, please visit https://www.newsfilecorp.com/release/170040

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