March 26, 2024

FDA Approves Medexus's Supplemental Biologics License Application for IXINITY(R) to Treat Hemophilia B in Pediatric Patients

Expanded indication includes patients under 12 years of age, based on Phase 3/4 data demonstrating safety and efficacy in previously treated patients in this age group

Toronto, Ontario and Chicago, Illinois--(Newsfile Corp. - March 26, 2024) - Medexus Pharmaceuticals (TSX: MDP) (OTCQX: MEDXF) today announced that the US Food and Drug Administration (FDA) recently approved Medexus's supplemental Biologics 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. IXINITY®, an intravenous recombinant factor IX therapeutic, is now approved for use in all patients with hemophilia B, a hereditary bleeding disorder characterized by a deficiency of clotting factor IX in the blood.

"We are pleased to secure approval for IXINITY for use in pediatric patients, a population that comprises approximately one third of individuals with hemophilia B in the United States*," said Ken d'Entremont, Chief Executive Officer of Medexus. "The newly expanded indication makes IXNITY a viable factor IX option for children living with hemophilia B. We hope the greater availability of IXINITY will help ease the burden on children and families who face the challenge of managing hemophilia B and allow children living with this lifelong condition to enjoy more active lives."

"IXINITY effectively prevented and controlled bleeding episodes in the Phase 3/4 pediatric study," commented Prof Johnny Mahlangu, BSc, MBBCh, MMed, FCPath, one of the study's principal investigators. "The study supported the efficacy and safety of IXINITY in pediatric patients, and the pharmacokinetics and safety profile were consistent with those observed in adults, although dose adjustment may be needed in pediatric patients. The results thus provide further validation of the clinical utility of IXINITY as a treatment for all people living with hemophilia B."

The sBLA and expanded indication for IXINITY® are based on results from a Phase 3/4 study that evaluated the pharmacokinetics (PK), safety, and efficacy of IXINITY® as a prophylactic treatment in previously treated pediatric patients under 12 years of age with severe or moderately severe hemophilia B. The study demonstrated that prophylaxis with IXINITY® was associated with low annualized bleeding rates, effective control of bleeding episodes, consistent PK, and a consistent safety profile. For more information about the study's methods, results, and conclusions, see "About the study" in Medexus's August 17, 2023 press release, available on the Investors-News & Events section of Medexus's

corporate website.

** Source: World Federation of Hemophilia Report on the Annual Global Survey 2021; www1.wfh.org/publications/files/pdf-2324.pdf (accessed March 7, 2024).*

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 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+ atwww.sedarplus.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, also known and/or referred to as "forward looking information" or "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 healthcare economic and other benefits of IXINITY® and expectations regarding the product's prospects. 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, and, in particular, Medexus's interpretation and assessment of the data presented by Medexus as summarized in this news release. 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 the assumptions are believed to be reasonable in the circumstances, these risks and uncertainties mean that actual results could differ, and could differ materially, from the expectations contemplated by 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 and determinations of the product's efficacy and cost-effectiveness in the context of a given facility (which varies by facility type). 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 and other protected names and marks in this news release 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.

Medexus sponsored the study and publication discussed in this news release, and Medexus employees and paid consultants participated in the authoring and editing of the publication.

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/203028

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