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# Medexus Enters into Exclusive License to Register and Commercialize Triamcinolone Hexacetonide (TH) in the United States with Ethypharm

## Drug shortage in the United States driving need for Triamcinolone Hexacetonide

TORONTO and CHICAGO and MONTREAL, Dec. 18, 2020 (GLOBE NEWSWIRE) -- Medexus Pharmaceuticals Inc. (the "**Company**" or "**Medexus**") (TSXV: MDP) (OTCQX: MEDXF) (Frankfurt: P731) is pleased to announce it has entered into an exclusive license agreement with Ethypharm ("**Ethypharm**") to register and commercialize Triamcinolone Hexacetonide Injectable Suspension 20 mg/mL ("**TH**") in the United States.

TH is indicated for intra-articular, intrasynovial, or periarticular use in adults and adolescents for the symptomatic treatment of subacute and chronic inflammatory joint diseases, including: rheumatoid arthritis, juvenile idiopathic arthritis (JIA), osteoarthritis and post-traumatic arthritis, synovitis, tendinitis, bursitis and epicondylitis. It is the longest-acting corticosteroid for intra articular injection, often lasting twice as long as competitive products.

The companies have agreed to a small upfront fee, which will be funded by Medexus with available liquidity, along with milestone payments at the time of FDA approval, at commercial product launch, and upon certain sales milestones. Medexus will also pay a double-digit royalty to Ethypharm on net sales of TH in the United States. TH has the potential to become the standard of care by offering a longer duration of action along with fewer injections (and by extension, fewer hospital visits and general anesthetics), as well as a safer and more cost-effective solution than competitive products. The Company expects to file for FDA approval of TH within 12-24 months.

Ken d'Entremont, Chief Executive Officer of Medexus, commented, "There has been a long-standing drug shortage of Triamcinolone Hexacetonide in North America due to previous manufacturing issues. Through the commercialization of Trispan, our Canadian product for the same indication, we have witnessed the urgency of providing patients with a solution firsthand. Our work with Health Canada prompted the FDA to reach out to us and inquire about the possibility of Medexus providing a similar solution in the United States. While we are committed to pursuing FDA approval for a commercial product launch, in the near term, we are engaged with the FDA's CDER Drug Shortage Staff in an effort to facilitate the import of finished drug product to address the ongoing drug shortage."

Ken d'Entremont continued, "This exclusivity agreement is a major step towards offering a critical solution for patients suffering from debilitating forms of joint disease in the United

States. The transaction is indicative of our continued efforts to bring in additional products and grow the Company both organically and inorganically. We will continue to look for additional opportunities to bring important specialty treatments to physicians and patients across North America.”

### **About the Ethypharm Group**

Ethypharm is a European pharmaceutical company focused on two therapeutic areas: the Central Nervous System and Critical Care. Ethypharm markets its drugs directly in Europe and China, and with partners in North America and the Middle East where its drugs are in high demand. The Group employs more than 1,500 people, mainly in Europe and China.

Ethypharm works closely with authorities and healthcare professionals to ensure the appropriate use of and access to its medicines, by as many people as possible.

### **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 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 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 certain payments to be made by Medexus in connection with the license, the potential for TH to become the standard of care, the Company’s intention to seek FDA approval, and the Company’s plans for future growth. 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 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; 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.



Source: Medexus Pharmaceuticals Inc

