



## **Virpax<sup>®</sup> Pharmaceuticals Announces Successful Completion of Pre-IND Meeting with FDA on Epoladerm<sup>™</sup> for the Management of Osteoarthritis of the Knee**

*505(b)(2) Regulatory Pathway and Proposed Study Design Is Acceptable*

*Virpax to Finalize IND and Prepare for Phase I Human Study*

**WEST CHESTER, PA – March 18, 2020** – Virpax<sup>®</sup> Pharmaceuticals Inc. (“Virpax”), a company specializing in developing pharmaceutical products for pain management by using new drug delivery systems, today announced that it has successfully completed a pre-Investigational New Drug (IND) Application meeting with the U.S. Food and Drug Administration (FDA) for Epoladerm<sup>™</sup> (diclofenac epolamine) spray, an investigational metered-dose topical aerosol of diclofenac epolamine supplied in a pre-filled device for administration as a topical spray film to the area of osteoarthritis of the knee. Epoladerm<sup>™</sup> is being developed in partnership with MedPharm Ltd. In the meeting, the FDA agreed that it is reasonable for Virpax to pursue a 505(b)(2) New Drug Application (NDA) for Epoladerm<sup>™</sup>, which is an abbreviated approval pathway allowing Virpax to reference safety and efficacy data of a reference listed drug. It was further indicated that the planned indication for Epoladerm<sup>™</sup> osteoarthritis of the knee is acceptable. Other guidance regarding study design was also provided.

MedPharm is working closely with Virpax to develop Epoladerm<sup>™</sup> (NSAID spray film) an investigational spray film designed to deliver an NSAID transdermally via a metered-dose spray. The delivery system features a high level of adhesiveness, accessibility and skin drying. Virpax filed a pre-IND meeting request with the U.S. Food and Drug Administration (FDA) and it was granted on January 22, 2020.

Given this feedback, Virpax plans to finalize its IND application and prepare for a Phase I pharmacokinetic study of Epoladerm<sup>™</sup> in humans.

“We believe our proprietary metered-dosed delivery system (Epoladerm<sup>™</sup>) could provide an effective tool in the management of osteoarthritis of the knee,” said Anthony P. Mack, CEO of Virpax. “We are looking forward to moving ahead with our planned studies and executing on our clinical milestones given this accelerated regulatory pathway.”

### **About Epoladerm<sup>™</sup>**

Virpax Pharmaceuticals is developing Epoladerm<sup>™</sup> (diclofenac epolamine) spray, an investigational metered-dose topical aerosol of diclofenac epolamine supplied in a pre-filled device for administration as a topical spray film to manage chronic pain associated with osteoarthritis of the knee. The proprietary Patch-in-a-Can technology offers the possibility of convenient twice a day dosing on the knee applied from a metered-dose aerosol canister. The spray film is thinner than a standard liquid bandage, it is visibly clear on the knee, and fast drying. As a spray, the formulation avoids the inconvenient messy handling of creams or gels that require patients to rub active onto the knee.

## **About Virpax Pharmaceuticals**

Virpax develops branded pharmaceutical products for pain management by using cutting-edge technology to enhance patients' quality of life. The company is focused on becoming a global leader in pain management by developing and delivering innovative pharmaceutical products to its customers. For more information, please visit [www.virpaxpharma.com](http://www.virpaxpharma.com).

## **About MedPharm Ltd.**

MedPharm is the world's leading contract provider of topical and transdermal product design and formulation development services. MedPharm are experts at reducing risk and accelerating development times for generic and proprietary pharmaceutical customers through their unique, cost-effective and industry-leading performance testing models. Well established as the global leaders in dermatology, nail, mucosal membrane, and transdermal product development, MedPharm can also offer innovative solutions for ophthalmic and airway preparations recognized for their scientific rigor by regulators and investors. MedPharm has fully established R&D centers in the USA and UK and has its global HQ in Guildford, UK.

## **Forward-Looking Statement**

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Virpax cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to, those associated with the timing of the OSF200 regulatory filings and clinical milestones and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and Virpax takes no obligation to update or revise these statements except as may be required by law.

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