https://www.businesswire.com/news/home/20180912005124/en/Virpax-Pharmaceuticals-Reports-Pre-IND-Guidance-FDA-DSF100

Virpax Pharmaceuticals Reports Pre-IND Guidance From FDA for DSF100

505(b)(2) Regulatory Pathway and Proposed Study Design Is Acceptable Virpax to Finalize IND and Prepare for Phase 1 Human Study

September 12, 2018 08:55 AM Eastern Daylight Time

MALVERN, Pa.--(BUSINESS WIRE)--Virpax Pharmaceuticals (“Virpax”), a company specializing in developing pharmaceutical products for pain management by using new drug delivery systems, received a written response from the US Food and Drug Administration (“FDA”) in lieu of a meeting regarding its pre-Investigational New Drug (“pre-IND”) application for DSF100 (1.3% 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 acute pain. DSF100 is being developed in partnership with MedPharm Ltd. In the response, FDA agreed that it is reasonable for Virpax to pursue a 505(b)(2) New Drug Application (NDA) for DSF100, which is an abbreviated approval pathway allowing Virpax to reference safety and efficacy data of a listed drug. The response further indicated that the planned indication for DSF100 of acute pain due to minor strains, sprains and contusions is acceptable. Other guidance regarding study design was also provided.

“We are looking forward to moving ahead with our planned studies and executing on our clinical milestones in an accelerated manner through this regulatory pathway.”

Tweet this

Given this feedback, Virpax plans to finalize its IND application and prepare for a Phase 1 study of DSF100 in humans. Additionally, Virpax intends to submit a Canadian Clinical Trial Application (CTA).

“We believe the advanced delivery system of DSF100 could provide an important tool in the management of acute pain without the use of opioid analgesics, which is a priority in today’s healthcare environment,” said Anthony P. Mack, CEO of Virpax. “We are looking forward to moving ahead with our planned studies and executing on our clinical milestones in an accelerated manner through this regulatory pathway.”

About DSF100

Virpax Pharmaceuticals is developing DSF100 (1.3% 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 acute pain. The unique Patch-in-a-Can™ technology potentially offers the possibility of long-term dosing of a product through the skin or mucosal membrane from a clear “patch” conveniently applied as a spray from a canister. Thinner than a standard liquid bandage, the aerosol spray is invisible. As a spray, this formulation manages to avoid the inconvenient mess of creams or gels that can be rubbed off by clothing or physical contact.

About Virpax Pharmaceuticals

Virpax Pharmaceuticals develops branded pharmaceutical products for pain management by using cutting-edge technology to enhance patients’ quality of life, all while creating value for its investors and partners. The company is focused on becoming a global leader in pain management by developing and delivering innovative pharmaceutical products to its customers. Virpax is based in Malvern, PA, USA. For more information visit www.virpaxpharma.com.

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 DSF100 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.