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Virpax Pharmaceuticals Announces Successful Pre-IND Meeting for LBL100

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12/27/18 08:55 AM EST

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

Virpax to Finalize IND and Prepare for Phase 1 Human Study

MALVERN, PA / ACCESSWIRE /December 27, 2018 / Virpax Pharmaceuticals ("Virpax"), a company specializing in developing pharmaceutical products for pain management by using new drug delivery systems, completed a successful pre-Investigational New Drug ("pre-IND") Meeting with the US Food and Drug Administration ("FDA") for LBL100.LBL100 is being developed in partnership with Lipocure Ltd. LB100 is an investigational product, (3% bupivacaine in Lipogel), being developed as a long-acting local anesthetic for post-operative pain.The FDA agreed that it is reasonable for Virpax to pursue a 505(b)(2) New Drug Application (NDA) for LBL100, which is an abbreviated approval pathway allowing Virpax to reference safety and efficacy data of a listed drug.

Given this feedback, Virpax plans to finalize its IND application and prepare for a Phase 1 study of LBL100 in humans. Additionally, Virpax intends to submit a Canadian Clinical Trial Application (CTA).

"Advances in the drug delivery of anesthetics are important to not only improve pain management for a longer period of time, but to also help reduce the need for opioid interventions, particularly in a post-operative setting," said Anthony Mack, CEO of Virpax. "We believe the advanced liposomal drug delivery technology licensed from LipoCure offers a significant step forward. We will move forward with plans to execute on our clinical milestones through this regulatory pathway."

About LBL100

LBL100 is a drug product based on a type of liposomal delivery system with large multi-vesicular vesicles (LMVVs) encapsulating a very high dose of the local anesthetic bupivacaine in a unique way. These drug-loaded liposomes are composed of lecithin and cholesterol; both lipids are "GRAS" (Generally Recognized As Safe). These LMVVs are embedded in hydrogel beads to form a Lipogel. The system delivers a local analgesic medicine from the Lipogel that is intended to provide improved onset, duration and peak performance properties. With early studies indicating it can provide pain control for up to 96 hours, the formulation has shown the potential to reduce reliance on opioid pain management to improve quality of care and hospital economics.

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 LBL100 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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SOURCE: Virpax Pharmaceuticals