# Virpax Pharmaceuticals Reports on FDA Pre-IND Response for NobrXiol™

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NobrXiol™, an intranasal cannabidiol product candidate for the treatment of epilepsy in both children and adults, has received pre-investigational new drug (PIND) guidance from the FDA.

Virpax® Pharmaceuticals, Inc., a company specializing in developing non-addictive products for pain management, post-traumatic stress disorder, central nervous system (CNS) disorders and viral barrier indications, announced that it has received pre-Investigational New Drug (PIND) application guidance from the U.S. Food and Drug Administration (FDA) for NobrXiol™, the Company's product candidate for the delivery of cannabidiol in the management of epilepsy in children and adults.

NobrXiol utilizes the Nanomerics Molecular Envelope Technology (MET) as its delivery system to cross the blood brain barrier, propelling the cannabidiol nanoparticles through the nose to the brain via the olfactory nerve.

The main purpose of a pre-IND submission is to obtain FDA guidance on the overall development plan for a new drug and to identify any need for further data prior to submitting the IND.

"Virpax now has guidance on how to proceed with the IND enabling studies and possible regulatory pathways to pursue for NobrXiol," stated Dr. Sheila A. Mathias, Chief Scientific Officer for Virpax. "Based on the written responses from the FDA and its recommendations, we believe that we can proceed with the next steps in the process towards an IND application for this product candidate."

"This is a significant step forward for the NobrXiol project and we are very pleased with the

outcome of the pre-IND meeting with the FDA," said Anthony P. Mack, Chairman and CEO of Virpax. "We believe this product candidate has potential benefits over existing oral CBD treatments for epilepsy including Dravet Syndrome and Lennox-Gastaut Syndrome. We believe that by using the MET delivery system there may be significant advantages for patients including fewer side effects, avoidance of drug-to-drug interaction and lower dosing of CBD required," concluded Mr. Mack.

Read the original article on Business Wire.