

# Virpax® Pharmaceuticals Announces Successful Completion of Pre-IND Meeting with FDA on NES100 for the Management of Acute and Chronic Pain

MALVERN, PA – March 2, 2020 – Virpax® 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 NES100 which uses the Nanomerics nanotechnology for the delivery of a metabolically labile intranasal peptide for the management of acute and chronic pain. NES100 is the first investigational product formulation delivered via the nasal route to enhance enkephalin transport to the brain. NES100 uses a preassembled device and cartridge to propel the enkephalin formulation through the nose to the brain via the olfactory nerve. The Nanomerics Molecular Envelope Technology (MET) will help to carry the drug to the brain to promptly suppress pain. NES100 has analgesic potential without the concerns for opioid tolerance and withdrawal, respiratory depression, euphoria or addiction.

A pre-IND meeting provides an opportunity for an open communication between the sponsor and the FDA to discuss the IND development plan and to obtain the agency's guidance for clinical studies for the sponsor's new drug candidate.

"We are very pleased with the outcome of the pre-IND meeting with the FDA," said Anthony P. Mack, Chairman and CEO, Virpax. "The initial pathway to move forward with the development of NES100 has been clarified and confirmed."

#### **About NES100**

NES100 is a drug product based on a type of nanotechnology. The nanotechnology enables the exclusive delivery of a metabolically labile peptide drug into the brain on intranasal delivery. NES100 is manufactured using industrially relevant equipment and processes (high pressure homogenization and spray drying). There is pharmacological evidence of activity of MET enabled enkephalin in morphine-tolerant animals. The MET nanoparticles are well tolerated via the nasal route at the dose administered. NES100 demonstrated comparable preclinical activity to morphine in all animal pain models tested without the drug seeking and tolerance associated with opioids.

## **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.

#### About Nanomerics Ltd.

Nanomerics is a specialty pharmaceutical company focused on the development of pharmaceutical products with enhanced bioavailability. Biocompatible polymers are tailored to form containers that package the drug and carry it across epithelial barriers to the target site. Nanomerics' proprietary technology is based on world leading know-how and scientific leadership in polymeric nanotechnology. The company's MET delivers a step change in target tissue availability of drugs and biological APIs such as peptides across a

number of epithelial barriers. The founding scientists Professor Ijeoma F. Uchegbu and Professor Andreas G. Schätzlein developed the technology at the Universities of Strathclyde and Glasgow and, latterly at the UCL School of Pharmacy.

### **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 NES100 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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