

# Virpax Advances Envelta<sup>TM</sup> Development with NCATS Under CRADA Agreement

# - Multiple Contracts Awarded to Support the Development and Manufacturing of Envelta (NES100) -

BERWYN, PA, November 10, 2021 — Virpax® Pharmaceuticals, Inc. ("Virpax" or the "Company") (NASDAQ: VRPX), a company specializing in developing product candidates for pain management, CNS disorders and anti-viral indications, today announced that the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) has awarded research and development contracts to support Good Manufacturing Practices (GMP) production of drug substance and drug product. as well as to support Good Laboratory Practices (GLP) toxicology, safety studies and preclinical efficacy studies. The NIH has contracted with a clinical research organization to conduct additional pre-clinical efficacy studies and procured a device to be used with the manufactured GMP drug product for preclinical and clinical studies. The NIH has also engaged a firm to manufacture Leu-enkephalin (L-ENK), the active ingredient in Envelta and a firm to manufacture the Molecular Envelope Technology (MET) that is used to carry the L-ENK to the brain to promptly suppress pain.

Envelta is Virpax's endogenous enkephalin intranasal spray for acute and chronic pain, including pain associated with cancer. IND-enabling studies for Envelta are being performed under a Cooperative Research and Development Agreement (CRADA) with NCATS entered into by Virpax in August of 2020.

"We are encouraged with the progress that has been made under the CRADA with NCATS and the NIH Helping to End Addiction Long-term (HEAL) initiative, as we believe that it may help Virpax develop an effective and safe alternative to conventional opioids used by patients to manage acute and chronic pain. In October 2021, Virpax announced that a \$1.87 million contract had been signed with Recro Pharma for the development, manufacturing, and stability studies of Envelta. Also, the NIH engaged Battelle to conduct Dose Range Finding Studies, with the first study in rats being completed on October 7<sup>th</sup>, 2021. A Dose Range Finding Study in dogs will start on November 10, 2021. With today's announcement, we believe we are well on our way to completing the required IND-enabling studies for Envelta. Once completed, it is our intention to immediately submit our IND package to the FDA so that we may begin human trials," commented Virpax's Chairman & CEO Anthony P. Mack.

#### About Envelta<sup>TM</sup>

Envelta is an investigational intranasal formulation intended to improve enkephalin transport to the brain. Enkephalin is a naturally occurring (endogenous) peptide that is not easily administered in its original form. Envelta uses a preassembled device and cartridge to propel the enkephalin formulation through the nose to the brain by flowing along the olfactory nerve pathway. The Molecular Envelope Technology is designed to protect the drug and help carry it to the brain, enabling it to cross the blood-brain barrier to suppress pain by binding to the delta-opioid receptors. Envelta<sup>TM</sup> has demonstrated analgesic potential in animal models without developing opioid tolerance, withdrawal, respiratory depression, euphoria, or addiction associated with the use of morphine. Once the Envelta IND-enabling studies are submitted to the FDA, the data may be cross-referenced to our cancer pain and PTSD INDs.

### **About Virpax Pharmaceuticals**

Virpax is developing branded product candidates for non-addictive pain management and neurological disorders using its proprietary technologies to optimize and target drug delivery. Virpax is initially seeking FDA approval of its three patented drug delivery platforms. Epoladerm<sup>TM</sup> is a topical diclofenac spray film formulation being developed to manage osteoarthritis pain. Probudur<sup>TM</sup> is a single injection long-acting liposomal bupivacaine formulation being developed to manage post-operative pain. Envelta<sup>TM</sup> is an intranasal Molecular-Envelope Technology (MET) enkephalin formulation being developed for the management of acute and chronic pain, including pain associated with cancer, as well as post-traumatic stress disorder (PTSD) under the name PES200. MET technology is also used in AnQlar<sup>TM</sup>, a candidate to inhibit viral replication caused by influenza or SARS-CoV-2. Virpax recently acquired global rights to VRP324, a product candidate for the nasal delivery of a pharmaceutical-grade cannabidiol (CBD) for the management of epilepsy in children (a rare pediatric disease) and adults. For more information, please visit www.virpaxpharma.com.

## **Forward-Looking Statement**

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's planned clinical trials, product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors, including the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on the Company's operations, clinical development plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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