Virpax Pharmaceuticals Recaps Milestones and Highlights Product Portfolio

BERWYN, PA / December 28, 2021 / Virpax® Pharmaceuticals, Inc. ("Virpax" or the "Company") (NASDAQ:VRPX) achieved significant milestones relating to its pipeline of product candidates as of the end of 2021, which are summarized below.

"I believe that Virpax has made significant progress this past year toward our stated goals," commented Anthony P. Mack, Chairman and CEO of Virpax. "These accomplishments include accelerated development of our existing product candidates, broadening our pipeline of product candidates, and utilizing grants where appropriate. We recently announced that we anticipate commencing our initial human trial for Epoladerm™ in the second quarter of 2022.

"Virpax initially focused strictly on pain product candidates. However, our unique Molecular Envelope Technology ('MET') delivery platform licensed from Nanomerics, Ltd. ('Nanomerics') has enabled the development of product candidates for central nervous system ('CNS') and anti-viral indications. In the second half of 2021, we advanced the development of AnQlar™, a prophylactic, over-the-counter ('OTC') anti-viral product candidate formulated to prevent the spread of respiratory infections like influenza, SARS-CoV-2 and rhinovirus. We added VRP324 which is an intranasally delivered cannabidiol ('CBD') formulation for the management of epilepsy in adults and children. Our Envelta™ IND-enabling studies, completed by the National Center for Advancing Translational Sciences ('NCATS') as a part of our Cooperative Research and Development Agreement ('CRADA'), determined that the MET intranasal delivery formulation bypasses the liver which we believe reduces drug-to-drug interaction concerns for treatments using this technology.

"On the corporate front, we strengthened our Board by appointing two new members adding expertise in commercialization and financial strategy. Additionally, in 2021 we raised approximately $58 million in aggregate gross proceeds from our initial public offering and an underwritten follow-on public offering. These funds are being used for research and development activities of our product candidates. We are on track to add accomplishments in 2022 and I remain confident that we have the significant financial strength to continue advancing our pipeline," concluded Mr. Mack.

Epoladerm™

Epoladerm is a diclofenac topical spray film product candidate that is being developed for pain associated with osteoarthritis of the knee. Virpax recently reported successful results of a Charles River Laboratories single dose toxicology and pharmacokinetic study of dermal administration of Epoladerm in minipigs as part of the required Investigational New Drug Application ('IND') enabling trials. Single-dose transdermal delivery of Epoladerm was well-tolerated in all minipigs. There were no treatment-related clinical observations, changes in body weight, or dermal irritation observed. The maximum plasma concentration (Cmax) was reached at 4 hours post-dose, and concentrations of plasma Epoladerm remained at 24-hour post-dose for all animals.

Upon completion of all the required IND enabling studies and subsequent review by the FDA, Virpax intends to conduct a Phase 1 study to evaluate the relative bioavailability and pharmacokinetics of Epoladerm™. Virpax recently announced the execution of a clinical trial agreement with Altasciences Company, Inc., to conduct this study in Canada. Virpax anticipates enrollment of the first patient by early second quarter of 2022.

Probudur™

Probudur is an injectable bupivacaine liposomal hydrogel for postoperative pain management which Virpax believes has improved onset and extended duration of action compared to existing treatment options. Additional pre-clinical trials are being conducted with Lipocure, the product developer, to improve the formulation to potentially enhance manufacturing efficiencies, prolong duration and extend patent protection. Once completed, we plan to perform seven preclinical animal studies as part of required FDA IND enabling trials.

Envelta™

Envelta is an endogenous enkephalin intranasal spray for acute and chronic pain, including pain associated with cancer. This product leverages Nanomeric's MET platform technology which Virpax licensed to deliver the endogenous enkephalin formulation through an intranasal delivery enabling the enkephalin to permeate the blood-brain barrier while bypassing the liver. This product candidate is being funded through an in-kind CRADA with the NCATS.

Virpax recently announced that under this CRADA, the National Institutes of Health has awarded multiple contracts to support the research, development and manufacturing of Envelta. These contracts are 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 has 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 company to manufacture the MET carrier that delivers L-ENK to the brain to promptly suppress pain.

AnQlar™

AnQlar (formerly MMS019) is a high-density intranasal molecular masking spray in development as an anti-viral OTC product for protection against respiratory infections, such as SARS-CoV-2 and influenza, that Virpax anticipates will be used as an adjuvant to barrier-based personal protective equipment. Virpax recently announced a manufacturing and supply agreement with Seqens to provide AnQlar for both clinical studies and the long-term commercial supply of AnQlar.

Additionally, Virpax engaged Sinclair Research to initiate IND-enabling studies for AnQlar. The Company anticipates that these preclinical animal studies will begin in early 2022.

VRP324

Virpax has acquired the exclusive worldwide rights from Nanomerics to use its MET platform for the nasal delivery of CBD for the management of epilepsy in children (a rare pediatric disease) and adults.

Under this agreement, Virpax has the global rights to develop, manufacture, market and sell VRP324, the first investigational formulation delivered via the nasal route to enhance CBD transport to the brain. This product candidate will be formulated to potentially treat seizures associated with tuberous sclerosis complex ('TSC'), Lennox-Gastaut syndrome and Dravet syndrome in patients one year of age and older. Lennox-Gastaut syndrome and Dravet syndrome are rare CNS diseases considered serious epileptic encephalopathies that cause epileptic seizures, as well as cognitive and behavioral changes, and are generally resistant to treatment. Preclinical studies of VRP324 have been initiated by Nanomerics which it anticipates will be completed in the first quarter of 2022. Upon completion, Virpax will collaborate with RRD International, a clinical drug development company which Virpax has engaged, to prepare the pre-IND briefing documents for the FDA.

About Virpax Pharmaceuticals

Virpax is developing branded product candidates for non-addictive pain management and neurological disorders using its proprietary technologies that optimize and target drug delivery. Virpax is initially seeking FDA approval of its three different patented drug delivery platforms. Epoladerm™ is a topical diclofenac spray film formulation being developed to manage pain associated with osteoarthritis of the knee. Probudur™ is a single injection long-acting liposomal bupivacaine formulation being developed to manage post-operative pain. Envelta™ 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™, a candidate to inhibit viral replication caused by influenza or SARS-CoV-2. Virpax 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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