Virpax® Pharmaceuticals Receives FDA Response and Guidance on MMS019

-- Company to Pursue Prophylactic Treatment Against SARS and Influenza for Daily Use as an OTC Product--

BERWYN, PA, August 17, 2021 — Virpax® Pharmaceuticals, Inc. ("Virpax" or the "Company") (NASDAQ:VRPX), a company specializing in developing product candidates for pain management, CNS and anti-viral indications, today announced that it has received a written pre-investigational new drug (pre-IND) response from the U.S. Food and Drug Administration (FDA) for MMS019, its patented and proprietary high-density molecular masking spray under development for use as an anti-viral barrier product. Virpax believes the results of the pre-IND response support further research on MMS019 as an intranasal protective that may limit transmission of the viruses to others. Virpax expects to move forward and pursue a New Drug Application (NDA) for MMS019 as a once daily intranasal treatment. The FDA has indicated that Virpax may pursue an NDA drug approval with the Office of Non-Prescription Drugs. The Company has engaged Syneos Health to assist with the optimal clinical trial design based on an efficient timeline.

"We are very pleased with the response from the FDA. We believe that the initial pathway to move forward with the development of MMS019 has been clarified," said Anthony P. Mack, Chairman and CEO of Virpax. "The pre-IND meeting provides an opportunity for open communication between the Sponsor and the FDA to discuss the IND development plan and to obtain the FDA's guidance for clinical studies for the new drug candidate. As our development program proceeds, we will define the strategy for our drug-device combination product candidate, MMS019, for use in an over-the-counter setting as we look to support a consumer-friendly OTC indication."

Virpax previously announced that it has completed in-vitro, ex-vivo (human mucosal cells) and in-vivo trials for this product candidate. MMS019 demonstrated inhibition of viral replication of SARS-CoV-2 and influenza in animals at much higher ranges than what is encountered by humans in the nasal passages; no adverse effects were observed during the studies. In addition to inhibition of viral replication, the animal studies also demonstrated decreased levels of the virus in animal brain tissue, a potentially important observation as recent studies have shown neurological conditions with survivors of severe Covid.

About MMS019

MMS019 is a drug product candidate based on a type of nanotechnology that enables the exclusive delivery of a metabolically labile peptide drug into the brain on intranasal delivery. MMS019 is manufactured using industrially relevant equipment and processes (high pressure homogenization and spray drying). There is pharmacological evidence of activity of molecular envelope technology (MET) enabled enkephalin in morphine-tolerant animals. The MET nanoparticles are well tolerated via the nasal route at the dose administered. MMS019 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 is developing branded, non-addictive pain management product candidates using its proprietary technologies to optimize and target drug delivery. Virpax is initially seeking FDA approval using its three patented drug delivery platforms. Epoladerm™ is a topical diclofenac metered-dose spray film formulation being developed to manage acute musculoskeletal pain and osteoarthritis. Probudur™ is a single injection liposomal bupivacaine formulation being developed to manage post-operative pain. Envelta™ is an intranasal molecular-envelope enkephalin formulation being developed to manage acute and chronic pain, including pain associated with cancer. Virpax is also using its intranasal Molecular Envelope Technology (MET) to develop its PES200 product candidate to manage post-traumatic stress disorder (PTSD) and its MMS019 product candidate to inhibit viral replication caused by influenza or SARS-CoV-2. For more information, please visit www.virpaxpharma.com.

Forward-Looking Statements

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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