Vistagen Announces European Patent Office Intention to Grant New PH80 Nasal Spray Patent for the Treatment of Migraine

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 13, 2023-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression, and other central nervous system (CNS) disorders, today announced that the European Patent Office (EPO) issued an intention to grant a patent for the treatment of migraine by nasal administration of PH80 nasal spray, one of the Company's five rapid-onset investigational neuroactive pherine therapeutics. The patent claims also include treatment administered at the onset of migraine symptoms and treatment of migraines associated with traumatic brain injury. The patent, once granted, will not expire until at least 2040. The U.S. Patent and Trademark Office (USPTO) recently granted a related U.S. patent for Vistagen's PH80 nasal spray for treatment of migraine and similar patent applications are pending in several additional major pharmaceutical markets.

PH80 is a clinical-stage investigational pherine nasal spray designed with a potential rapid-onset mechanism of action (MOA) that is fundamentally differentiated from all currently approved treatments for migraine. PH80's proposed MOA does not require systemic exposure to produce a therapeutic effect, providing a significant potential treatment advantage over traditional pharmaceuticals targeted at the CNS, including current treatments for migraine. PH80 nasal spray initiates neural impulses in the olfactory bulb transmitted by pathways that rapidly affect the function of multiple structures in the brain, including the amygdala and hypothalamus, which have been linked to the pathology of migraine.

About PH80

PH80 nasal spray is a first-in-class, rapid-onset product candidate, designed to be used in a manner analogous to a rescue inhaler for asthma, with user-friendly, patient-tailored intranasal administration as-needed up to multiple times daily. The proposed rapid-onset mechanism of action of PH80 nasal spray is fundamentally differentiated from all currently approved treatment options for migraine and does not require systemic uptake or direct action on CNS neurons. PH80 has demonstrated an excellent safety profile in all clinical trials to date. Vistagen's PH80 development program is currently focused on both the acute management of menopausal hot flashes and acute treatment of migraine.

About Migraine

Migraine affects more than one billion individuals each year across the world and is one of the most common neurological disorders. Migraine is characterized by recurrent attacks of moderate to severe throbbing and pulsating pain on one side of the head and, left untreated, can last from four to 72 hours with debilitating symptoms such as nausea, vomiting, and increased sensitivity to light, noise, and odors. While approved treatments exist for migraine, many individuals could benefit from safer and more efficacious treatment options.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. Vistagen is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those currently available for treating anxiety, depression and multiple CNS disorders. Vistagen's pipeline includes six clinical-stage product candidates, including five investigational agents belonging to a new class of neuroactive drugs known as pherines, in addition to AV-101, an oral antagonist of the glycine site of the N-methyl-D-aspartate receptor (NMDAR). Pherines, which are administered as nasal sprays, are designed with an innovative rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can selectively and beneficially impact key neural circuits in the brain without requiring systemic uptake or direct activity on CNS neurons. Vistagen's AV-101 inhibits activity of the ion channel of the NMDAR but does not block it, unlike some approved therapeutics having significant side effects. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety, depression and several other CNS disorders. Connect at www.vistagen.com.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by Vistagen and its management, are inherently uncertain. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or development may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that the scope of protection and enforceability provided by any patents issued for any of the Company's drug candidates, including PH80, will be sufficient to deter competition, or that any of the Company's drug candidates, including PH80, will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's ability to secure adequate financing for its operations, including financing or collaborative support for continued clinical development of the Company's product candidates; other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials; fluctuating costs of materials and other resources and services required to conduct the Company's ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's drug candidates. These risks are more fully discussed

in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2022, and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). The Company's SEC filings are available on the SEC's website at www.sec.gov. Additionally, you should not place undue reliance on these forward-looking statements in the future, because they apply only as of the date of this press release and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

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