Vistagen Broadens PH80 Global Intellectual Property Portfolio with New Patents for the Treatment of Migraine

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 9, 2024-- Vistagen (Nasdaq: VTGN), a clinical-stage neuroscience-focused biopharmaceutical company dedicated to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on nose-to-brain neurocircuitry, today announced the broadening of its global intellectual property portfolio after receiving multiple new patents related to the use of PH80 for the treatment of migraine. PH80 is a non-systemic, hormone-free investigational pherine nasal spray in development as a rapid-onset treatment for vasomotor symptoms (hot flashes) due to menopause, with the potential to also treat premenstrual dysphoric disorder, dysmenorrhea, and migraine.

The new patents complement previously granted PH80 U.S. Patent No. 11,419,881 and EPO Patent No. 3955933 for the treatment of migraine. All of the new patents are expected to be in effect until 2040, subject to possible patent term extensions on a country-by-country basis.

- *Australia*: IP Australia issued a Notice of Allowance;
- *Hong Kong*: The Hong Kong Special Administrative Region – Intellectual Property Department issued Patent No. 40068177;
- *Japan*: The Japan Patent Office issued Patent No. 7476229; and
- *Mexico*: The Mexican Institute of Industrial Property issued a Notice of Allowance.

About PH80 Nasal Spray

PH80 is an investigational neuroactive pherine nasal spray with a novel neurocircuitry-focused mechanism of action (MOA) that is fundamentally differentiated from all currently approved treatment options for women's health indications. PH80's proposed MOA does not require systemic absorption or direct activity on neurons in the brain. Vistagen is developing PH80 as a potential new hormone-free treatment for the management of vasomotor symptoms (hot flashes) due to menopause, with additional potential in premenstrual dysphoric disorder, migraine, and dysmenorrhea.

About Pherines

Pherines are a novel class of synthetic neurocircuitry-focused drug candidates for psychiatric and neurological disorders. They are odorless and tasteless neuroactive steroids, delivered only intranasally, each with a differentiated mechanism of action (MOA) and safety profile from all currently approved drugs. Our neuroactive pherines rapidly activate olfactory system neurocircuitry to achieve therapeutic effects via nose-to-brain neural connections. Through these connections, pherines activate neural circuitry to specific brain regions that impact the neuroscience disorders we are targeting, without requiring systemic absorption or central nervous system (CNS) uptake. As a result of their novel non-systemic MOAs, our pherine drug candidates have demonstrated favorable and differentiated safety profiles in all clinical trials completed to date.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a clinical-stage neuroscience-focused biopharmaceutical company dedicated to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on its pioneering approach and deep understanding of nose-to-brain neurocircuitry. Designed exclusively as nasal sprays administered at microgram level doses, Vistagen's diversified pipeline of pherine product candidates rapidly activate chemosensory neurons in the nasal cavity to impact olfactory system and brain neurocircuitry. Favorable safety profiles have been observed in all clinical studies of Vistagen's pherine product candidates completed to date. Vistagen's neuroscience pipeline also includes an oral prodrug with the potential to modulate NMDA receptor activity in multiple neurological conditions, such as levodopa-induced dyskinesia associated with Parkinson's disease therapy and neuropathic pain. At Vistagen, we are passionate about creating novel and differentiated treatments that set new standards of care for millions of people living with anxiety, depression, and other neurological 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 Therapeutics, Inc. (Vistagen or the Company) 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 replicate past preclinical studies and/or clinical trials, 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 delays in launching, conducting and/or completing ongoing and planned nonclinical studies and clinical trials; the period over which the Company anticipates its available financial resources will fund its operating expense;

the timing of completion of preclinical studies and clinical trials and related preparatory work required to apply for and maintain regulatory approval for any of our product candidates; fluctuating costs of materials and other resources and services required to conduct the Company's ongoing and/or planned clinical and nonclinical 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 product 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, 2024, 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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