Vistagen and Fuji Enter Exclusive Negotiation Agreement for a Potential License to Develop and Commercialize Vistagen's Investigational Menopausal Hot Flash Therapy, PH80 Nasal Spray, in Japan

September 5, 2023

Vistagen to receive $1.5 million and Fuji to obtain time-limited exclusive negotiation period for the Japanese market

Recently reported exploratory Phase 2A study in women diagnosed with menopausal hot flashes demonstrated PH80's statistically significant reduction in the number of hot flashes and the severity, disruption in function, and sweating related to hot flashes as compared with placebo

SOUTH SAN FRANCISCO, Calif. & TOKYO--(BUSINESS WIRE)--Sep. 5, 2023-- Vistagen (Nasdaq: VTGN), a clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression, and other central nervous system (CNS) disorders, and Fuji Pharma Co., Ltd. ("Fuji") (TSE: 4554), a pharmaceutical company specializing in development, manufacture and marketing in the fields of women's healthcare and acute medical care, today announced they have entered into a time-limited (up to approximately eighteen months) agreement to negotiate exclusively with each other regarding a potential license to develop and commercialize Vistagen's PH80 in Japan, including for the acute treatment of moderate to severe vasomotor symptoms (hot flashes) due to menopause and potentially other indications. Vistagen's PH80 neuroactive nasal spray demonstrated statistically significant efficacy versus placebo in an exploratory double-blind, placebo-controlled Phase 2A study in women diagnosed with menopausal hot flashes. Fuji will make a non-refundable payment of $1.5 million to secure the time-limited exclusive negotiation rights for the Japanese market.

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"As we have seen across our neuroactive pherine nasal spray pipeline, PH80 offers exciting potential to transform a significant segment of a major healthcare market, including the current treatment landscape for women's healthcare," said Shawn Singh, CEO of Vistagen. "Menopausal hot flashes affect millions of women worldwide. We share Fuji Pharma's long-standing commitment to deliver innovative treatment options with potential to enable women to improve their physical, mental and social well-being. As we continue to advance our PH80 development program in the U.S., we look forward to continuing our ongoing discussions with Fuji regarding a potential development and commercialization collaboration in Japan."

"Our core mission at Fuji Pharma centers on helping people lead healthy lives by offering excellent pharmaceutical solutions. We believe that PH80 will provide new treatment options to improve the quality of life and further strengthen our position as one of the best Japanese specialty pharmaceutical companies in women's health," said Takayuki Iwai, President & CEO of Fuji. "We will continue to engage in dialogue with Vistagen, anticipating that successful development of PH80 will contribute to women's health in Japan."

About PH80

PH80 is a rapid-onset neuroactive pherine nasal spray product candidate designed to be used in a manner analogous to a rescue inhaler for asthma, taken by patients as-needed up to multiple times daily. Several pharmacokinetic and toxicokinetic studies show that PH80 administered intranasally is below the level of detection in plasma of human subjects and laboratory animals. Based on other studies conducted by Vistagen, pherine molecules have no detectable uptake in the brain and do not absorb systemically. All these data, along with the minimal adverse events reported in all clinical studies to date, demonstrate the excellent safety profile of this new class of molecules. In a placebo-controlled exploratory Phase 2A clinical trial, PH80 demonstrated an excellent safety profile and potential as a new treatment for moderate to severe vasomotor symptoms (hot flashes) associated with menopause.

About Vasomotor Symptoms (Hot Flashes) due to Menopause

Hot flashes are vasomotor symptoms (VMS) commonly experienced by women in menopause and are accompanied by hallmark symptoms such as sudden feelings of warmth, night sweats and flushed skin. Presentation of hot flashes is directly linked to changes in hormone levels due to menopause, or to menopause induced by other medical treatments or co-existing conditions, and the causal mechanism is unclear. Hot flashes are the most common symptom of the menopausal transition, affecting about 75% of menopausal women and about 40% of women in perimenopause. Current pharmacotherapies to treat hot flashes include hormonal therapy (estrogen with or without progesterone, or a synthetic progestin), gabapentins, certain antidepressants, clonidine and fezolinetant, a neurokinin 3 (NK3) receptor antagonist, all of which are associated with certain side effects.

About Exploratory Phase 2A Study of PH80 in Vasomotor Symptoms (Hot Flashes) due to Menopause

In a randomized, double-blind, placebo-controlled exploratory Phase 2A clinical study of PH80 (n=36) designed to explore the efficacy, safety and tolerability of intranasal administration of PH80 for the acute management of menopausal hot flashes in women, PH80 induced significant reduction in the daily number of hot flashes compared to placebo at the end of the first week of treatment, and the improvement was maintained through each treatment week until the end of the treatment period. At baseline, subjects reported a mean daily number of hot flashes of 7.7 (PH80, n=18) and 8.0 (placebo, n=18). After one week of treatment, the number of hot flashes dropped to 2.8 (PH80) and 6.4 (placebo) ($p<0.001$) and after four weeks of treatment the number of hot flashes dropped to 1.5 (PH80) and 5.1 (placebo) ($p<0.001$). PH80 treatment also significantly reduced the severity, disruption in function and sweating related to hot flashes during the treatment period as compared with placebo. This exploratory Phase 2A study of PH80 was conducted in a real-world setting in Mexico and was sponsored by Pherin Pharmaceuticals (Pherin), now a wholly owned subsidiary of Vistagen, prior to Vistagen's acquisition of Pherin in February 2023. Ellen Freeman, Ph.D. of the University of Pennsylvania served as the Principal Investigator of the study.

About Vistagen

Vistagen (Nasdaq: VTGN) is a 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 the treatment of anxiety, depression and multiple CNS disorders. Vistagen's pipeline includes six clinical-stage product candidates, including fasedienol (PH94B), itruvone (PH10), PH80, PH15, and PH284, with each of these being an investigational agent belonging to a new class of drugs known as pherines, as well as AV-101, which is an oral prodrug of an antagonist of the N-methyl-D-aspartate receptor (NMDAR). Pherines are neuroactive nasal sprays designed with an innovative proposed mechanism of action that activates chemosensory neurons in the nasal cavity and can beneficially impact key neural circuits in the brain without systemic absorption or direct activity on neurons in the brain. 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.

About Fuji

Fuji is a Tokyo Stock Exchange (TSE) listed, Japan-based pharmaceutical company mainly engaged in the manufacture and sale of prescription based pharmaceutical products. Since our establishment in 1965, Fuji has promoted corporate philosophy that "We help people lead healthy lives by offering excellent pharmaceuticals." and "Our corporate growth is proportional to our personal growth." Fuji focuses on the field of women's health care with a wide variety of new and generic drugs for women's specific diseases such as infertility, dysmenorrhea, endometriosis, contraception, and menopausal disorders. Fuji aims to be a leading company in women's healthcare and support health of women of all ages. https://www.fujipharma.jp

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 any of the Company's drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful, or that the Company will be able to successfully replicate the result of past studies of its product candidates, including PH80. 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; the scope and enforceability of the Company's patents, including patents related to PH80 and the Company's other pherine drug candidates; 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, 2023, and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, 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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