



SOUTH SAN FRANCISCO, Calif. and SHANGHAI, June 25, 2020 /PRNewswire/ -- [VistaGen Therapeutics](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) diseases and disorders with high unmet need, and EverInsight Therapeutics Inc., a biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products that address critical unmet medical needs for patients in Greater China and other parts of Asia, today announced they have entered into a strategic licensing and collaboration agreement for the clinical development and commercialization of PH94B, VistaGen's novel, rapid-onset neurosteroid drug candidate for multiple anxiety-related disorders, in Greater China, South Korea and Southeast Asia. In December 2019, VistaGen received Fast Track designation from the U.S. Food and Drug Administration (FDA) for development of PH94B for treatment of social anxiety disorder (SAD), the FDA's first Fast Track designation for a SAD drug candidate. The goal of the collaboration is to advance and support Phase 3 development and commercialization of PH94B as a potentially groundbreaking anti-anxiety medicine for patients in Greater China and other important Asian markets.



"We are pleased to collaborate with EverInsight, a company that shares our vision and excitement for bringing PH94B, a potentially transformative treatment for multiple anxiety disorders, to millions of individuals with unmet needs around the world. EverInsight is an ideal partner to support Phase 3 clinical development and commercial launch of PH94B in Greater China and other Asian markets, as we continue to focus on those activities in the U.S.," stated [Shawn Singh, Chief Executive Officer of VistaGen](#). "Anxiety, including social anxiety disorder, is a common and potentially debilitating illness that can have significant emotional, functional and economic effects on those who suffer, as well as their families, friends and colleagues. With the recent onset of mental health stressors associated with the COVID-19 pandemic and social justice unrest, the rising prevalence of anxiety, depression, and suicide is alarming. PH94B has a fundamentally different mechanism of action than all current treatments for social anxiety disorder and numerous other anxiety disorders, arguably the first new rapid-onset mechanism of action for treatment of anxiety in several decades. Our strategic collaboration today with EverInsight positions PH94B one step closer to becoming a potentially paradigm-shifting new treatment alternative for individuals worldwide."

"We partner with innovative companies that develop novel medicines with large commercial potential in Greater China and other Asian markets. PH94B is an extremely valuable asset that the world desperately needs today to provide potential relief from the debilitating impact of anxiety on daily life," said Sean Cao, Managing Director of CBC Group, which is currently funding EverInsight. "We are delighted to partner with VistaGen's team and are highly confident in our plan to advance PH94B through the necessary clinical development and approval process focused on successful

commercialization in our core markets."

#### **About VistaGen**

VistaGen Therapeutics is a multi-asset, clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and certain CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's [pipeline](#) is focused on three clinical-stage CNS drug candidates, each with a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in multiple large and growing CNS markets. For more information, please visit [www.vistagen.com](http://www.vistagen.com) and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

#### **About EverInsight Therapeutics**

EverInsight Therapeutics Inc. is a biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products that address critical unmet medical needs in CNS and ophthalmology for patients in Greater China and other Asian markets. The management team of EverInsight Therapeutics has deep expertise and an extensive track record of high-quality clinical development, regulatory affairs, CMC, business development and operations both in China and with leading global pharmaceutical companies. EverInsight Therapeutics is currently funded by the CBC Group.

#### **About CBC Group**

CBC Group (formerly C-Bridge Capital) is one of the largest and most active healthcare-dedicated investment firms in Asia focused on platform-building and buyout opportunities across three core areas within the healthcare sector: pharmaceutical & biotech, medtech and healthcare services. CBC's operationally intensive approach empowers healthcare sector champions to make transformative changes to enable sustainable long-term growth, fulfill unmet medical needs and continuously improve the standard of living and quality of care in China and the rest of Asia. Founded in 2014, CBC has a strong team of investment, healthcare and portfolio management professionals based across Singapore, Shanghai, Beijing, Hong Kong and New York.

#### **About PH94B**


PH94B is a first-in-class, odorless, rapid-onset (within approximately 15 minutes) synthetic neurosteroid nasal spray with therapeutic potential across a broad range of anxiety-related disorders. Easily self-administered in microgram doses, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects. VistaGen is initially developing PH94B as a potential fast-acting, non-sedating, non-addictive new generation acute treatment of social anxiety disorder (SAD), as well as for adjustment disorder with anxiety related to the COVID-19 pandemic. With its rapid-onset pharmacology, lack of systemic exposure and excellent safety profile, PH94B also has potential as a novel treatment for postpartum anxiety, post-traumatic stress disorder, preoperative anxiety, panic disorder and other anxiety-related disorders. VistaGen is preparing for Phase 3 clinical development of PH94B for SAD and Phase 2A development for AjDA associated with the COVID-19 pandemic. The FDA has granted Fast Track designation for development of PH94B as a treatment for SAD, the first such designation by the FDA for SAD. [View more background information on SAD and a video on PH94B's mechanism of action.](#)

#### **Forward-Looking Statements**

Various statements in this release are "forward-looking statements" concerning VistaGen's future expectations, plans and prospects, including: the potential of PH94B to be a paradigm shift in the treatment of SAD and other anxiety-related disorders; the potential for successful development and commercialization of PH94B in the U.S. and the EverInsight markets, including the Territory; and expectations for future milestones and royalties under the collaboration described herein. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: development and review of PH94B may not be achieved in any market; regulatory authorities in the U.S. or in the EverInsight markets, including the Territory, may decide that the design or results of the PH94B clinical program are not sufficient for regulatory approval for acute treatment of SAD or any other indication; development of PH94B may not be successful in any indication; success in nonclinical studies or in earlier stage clinical trials may not be repeated or observed in ongoing or future studies which may not support further development or be sufficient to gain regulatory approval to market the product; adverse events may be encountered at any stage of development that negatively impact further development; and even if development efforts are successful there may be events that limit market potential or trigger reductions in milestones or royalties under the collaboration described herein. Other risks and uncertainties include, but are not limited to, issues related to: adverse domestic and foreign healthcare reforms and changes of laws and regulations; general industry and market conditions; changes in interest rates and currency exchange rates; manufacturing and marketing risks, which include, but are not limited to, inadequate capacity to meet demand and unavailability of raw materials; entry of competitive products; and other technical and other unexpected hurdles in the development, manufacture and commercialization of PH94B, as well as those risks more fully discussed in the section entitled "Risk Factors" in VistaGen's most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in either company's other filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the companies' views only as of today, and should not be relied upon as representing their views as of any subsequent date. The companies explicitly disclaim any obligation to update any forward-looking statements.



# VistaGen® Therapeutics

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