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VistaGen Therapeutics Appoints Dr. Michael Liebowitz to CNS Clinical and Regulatory Advisory Board in Preparation for Pivotal Phase 3 Development of PH94B as the First Rapid-Acting, On-Demand Treatment of Social Anxiety Disorder

SOUTH SAN FRANCISCO, Calif., Oct. 15, 2018 (GLOBE NEWSWIRE) -- [VistaGen Therapeutics Inc](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet need, today announced the appointment of Michael Liebowitz, M.D. to the Company's CNS Clinical and Regulatory Advisory Board in preparation for pivotal Phase 3 development of PH94B as the first rapid-acting, on-demand treatment for social anxiety disorder (SAD), a debilitating social phobia which affects as many as 15 million American adults.

"We are extremely pleased to be working with Dr. Liebowitz to prepare for and advance PH94B through our pivotal Phase 3 program for SAD. He is a pioneer and internationally recognized leader in the field of anxiety disorders who will continue to shape and inform the future of these therapies in his role as a member of our CNS Clinical and Regulatory Advisory Board," said [Mark Smith](#), M.D., Ph.D., Chief Medical Officer of VistaGen. "Dr. Liebowitz has done life-changing work in addressing the widespread affliction of SAD. He has not only conducted many clinical trials in SAD, but he also developed the Liebowitz Social Anxiety Scale, or LSAS, which is widely-used as a primary outcome measure in clinical research on SAD, as well as for evaluation in clinical practice. Most importantly, we share his passion in helping patients. His decades of expertise will add enormous value to our efforts to provide a new and more effective treatment to the millions of people who are suffering from this debilitating condition."

Dr. Liebowitz is a Columbia University psychiatrist and former director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute. He retired in 2006 as Director of the Anxiety Disorder Clinic, a position that he held since 1982, and is a member of the American Society of Clinical Psychopharmacology, Anxiety Disorder Association of America Scientific Advisory Board, American College of Neuropsychopharmacology and American Psychiatric Association. He is also Managing Director of The Medical Research Network LLC and serves on the editorial board of *Depression and Anxiety*. Dr. Liebowitz has published numerous journal articles, books and chapters about psychiatry.

"Due to the predictable occurrence of various performance and social situations that individuals with SAD fear and avoid, an effective, rapidly-acting treatment for the symptoms of SAD would be extremely valuable and life-changing for those individuals," commented Dr. Liebowitz. "VistaGen's PH94B presents a valuable opportunity for both the company and those affected by SAD. I am delighted to be working with VistaGen's team to continue prior progress with PH94B. I believe pivotal studies of PH94B have exciting potential to demonstrate its usefulness in alleviating symptoms of social anxiety disorder and other anxiety states where rapid, on-demand relief would be of benefit to patients."

About PH94B

PH94B was developed from proprietary compounds called pherines. Administered as a nasal spray, PH94B acts locally on peripheral nasal chemosensory receptors that trigger rapid activation of the limbic system areas of the brain associated with SAD. This mechanism of pharmacological action, the rapid onset of efficacy, and the excellent safety and tolerability profile shown in clinical trials make PH94B an excellent product candidate for the acute intermittent and long-term treatment of individuals with SAD.

About Social Anxiety Disorder

Social Anxiety Disorder, SAD, is a debilitating social phobia affecting as many as 15 million American adults and is the fourth most common psychiatric condition after depression, specific phobias and substance use.¹ SAD is

characterized by a persistent and unreasonable fear of one or more social or performance situations, where the individual fears that he or she will act in a way or show symptoms that will be embarrassing or humiliating, leading to avoidance of the situations when possible and anxiety or distress when they occur.¹ These fears have a significant impact on the person's employment, social activities and overall quality of life. Currently, only antidepressants, administered chronically, are FDA-approved for treatment of SAD. However, such antidepressants have a slow onset of effect (often several weeks to months) and have a range of known side effects that may make them unattractive to individuals often situationally affected by SAD.

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for multiple CNS diseases and disorders with high unmet need. For more information, please visit www.vistagen.com and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Forward-Looking Statements

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development of PH94B for SAD constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that (i) we may encounter unexpected adverse events in patients in our clinical studies of PH94B that cause us to discontinue further development of PH94B, (ii) we may not be able to successfully demonstrate the safety and efficacy of PH94B in late-stage clinical development, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future PH94B studies, and ongoing or future clinical results may not support further development or commercialization of PH94B or be sufficient to gain regulatory approval to market PH94B for SAD or any other CNS disease or disorder, (iv) decisions or actions of regulatory agencies may negatively affect the initiation or progress of ongoing or future PH94B clinical trials, and our ability to proceed with further clinical studies or to obtain marketing approval, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for PH94B, (vi) we may not have access to or be able to secure substantial additional capital required to support our operations, including the potential pivotal Phase 3 clinical development of PH94B activities described above, and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of PH94B. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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¹ <https://adaa.org/understanding-anxiety/social-anxiety-disorder>



Source: VistaGen Therapeutics, Inc.