VistaGen Therapeutics Receives AV-101 Japanese Patent for Treatment of Depression and Hyperalgesia

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SOUTH SAN FRANCISCO, Calif., Feb. 19, 2019 (GLOBE NEWSWIRE) -- VistaGen Therapeutics (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders with high unmet need, today announced that the Japan Patent Office (JPO) has issued a patent related to methods of treating depression with AV-101, VistaGen's oral NMDA receptor glycine site antagonist in Phase 2 development for treatment of major depressive disorder (JP 6436913B). This patent also relates to methods of treating hyperalgesia, which is extreme sensitivity to pain. The new AV-101 Japanese patent will not expire until at least 2034.

"Development and commercialization of our CNS pipeline in Japan, together with the U.S., China and the European Union, is among our top corporate priorities, stated Shawn Singh, Chief Executive Officer. "Together with our previously obtained Japanese patent for the synthesis of AV-101, this key patent now expands commercial protection of AV-101 in Japan, one of the world's largest pharmaceutical markets, a market with a strong long-term track record of innovative and successful neuropsychiatry products."

About AV-101
VistaGen's AV-101 (4-Cl-KYN) is an investigational, oral NMDA receptor glycine site antagonist with potential to be a treatment for multiple CNS indications with high unmet need. AV-101 is currently in Phase 2 clinical development in the U.S. for major depressive disorder (MDD) and in a first-step target engagement study in healthy volunteer U.S. military Veterans for suicidal ideation. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for development of AV-101 as both a potential adjunctive treatment of MDD and as a non-opioid treatment for neuropathic pain.

About Major Depressive Disorder (MDD)
MDD affects nearly 300 million people of all ages globally and is the leading cause of disability worldwide. Individuals with depression, including MDD, experience continuous suffering from a serious, biologically based disease which has a significant negative impact on all aspects of life, including quality of life. While current antidepressants are widely used for treatment, large-scale studies have suggested that the drug-treated MDD market is substantially underserved by current medications.

About VistaGen
VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines with for multiple CNS diseases and disorders with high unmet need. Each of VistaGen's CNS pipeline candidates has potential as a convenient, at-home treatment with rapid-onset therapeutic benefits and an exceptional safety profile - without psychological or other side effects and safety concerns often associated with current and potential new generation medications for certain highly-prevalent CNS diseases and disorders, such as major depressive disorder, neuropathic pain and social anxiety disorder. Each CNS drug candidate in VistaGen's pipeline is either currently in, or has completed, Phase 2 clinical development. AV-101, an oral NMDA receptor glycine antagonist, is in Phase 2 development in the U.S. for treatment of MDD and in a first-step target engagement study in healthy volunteer U.S. military Veterans for suicidal ideation. The FDA has granted Fast Track designation for development of AV-101, both as a potential adjunctive treatment of MDD and as a non-opioid treatment for neuropathic pain. PH10 nasal spray is a potential first-in-class CNS neuroactive steroid with rapid onset effects observed at microgram doses and without systemic exposure. PH10 is in Phase 2 development for MDD. PH94B nasal spray also is a potential first-in-class CNS neuroactive steroid with rapid onset effects observed at microgram doses and without systemic exposure. Phase 2 development has been completed successfully, and PH94B is now being prepared for Phase 3 as an on-demand PRN treatment of Social Anxiety Disorder (SAD).

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 and commercialization of our drug candidates, including AV-101 for MDD, neuropathic pain and suicidal ideation, PH94B for SAD, and PH10 for MDD, as well as our intellectual property and commercial protection of our drug candidates, all of which 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 during our clinical development of any product candidate that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates at each stage of clinical development, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future studies, and ongoing or future preclinical and clinical results may not support further development of, or be sufficient to gain regulatory approval to market AV-101, PH94B, and/or PH10, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our product candidates. 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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