VistaGen Therapeutics Announces USPTO Grant of Patent for Treatment of Depression with Fast-Acting PH10 Neuroactive Nasal Spray

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Previously completed Phase 2a clinical study of PH10 demonstrated significant antidepressant effects without psychological side effects or safety concerns after only one week of administration

Phase 2b clinical trial for treatment of Major Depressive Disorder (MDD) planned for second half 2020

SOUTH SAN FRANCISCO, CA / ACCESSWIRE / July 23, 2019 / VistaGen Therapeutics (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 that the U.S. Patent and Trademark Office (USPTO) has granted U.S. Patent No. 10,322,138 related to methods of treating major depressive disorder (MDD) with VistaGen's PH10 neuroactive nasal spray, a potential first-in-class, neurosteroid administered in microgram doses for treatment of MDD. The newly granted patent will not expire until at least 2034. Counterpart foreign patents have already been issued in China, Europe, Japan and several other countries.

"We continue to assemble a strong portfolio of patents related to our CNS drug pipeline. This newly granted patent is a key component of our commercial protection strategy for PH10 in the U.S.," stated Shawn Singh, Chief Executive Officer of VistaGen. "Based on positive results of an exploratory Phase 2a study of PH10 as a stand-alone therapy for MDD, during which rapid-onset antidepressant effects were observed at microgram doses, without systemic exposure, psychological side effects or safety concerns, we are preparing for Phase 2b clinical development of PH10 in 2020, initially as a novel, fast-acting, at-home stand-alone treatment for MDD."

"MDD affects approximately 16 million adults in the U.S. and is a common and potentially debilitating illness that can have profound emotional, functional and economic impact on both those who suffer from the disorder and their loved ones. The impact of depression is greatest for those who do not benefit from standard treatments currently available. With both PH10 and AV-101, our novel oral NMDA receptor antagonist currently in Phase 2 development as an add-on treatment for MDD, our goal is to help fill the void of inadequate current therapies for MDD and transform the treatment landscape for individuals with MDD. Unfortunately, there is no 'one size fits all' solution for depression. With their unique mechanisms of action, we believe both AV-101 and PH10 have potential for multiple applications in global depression markets, as stand-alone therapies, or as add-on therapies to augment current FDA-approved antidepressants, and to prevent relapse following successful treatment with ketamine-based therapies," continued Mr. Singh.

PH10 for MDD, Phase 2a Study and Next Steps:

In an exploratory 30-patient Phase 2a clinical study, PH10 was well-tolerated and, at microgram doses, demonstrated rapid-onset antidepressant effects, as measured by the Hamilton Depression Rating Scale (HAM-D), without psychological side effects or safety concerns. VistaGen is planning Phase 2b clinical development of PH10 in 2020 initially as a new stand-alone treatment for MDD. With its exceptional safety profile during clinical development to date, PH10 also has potential to change the current paradigm for treatment of treatment-resistant depression (TRD) with ketamine-based therapy (intravenous ketamine or esketamine nasal spray, both of which must be administered in a clinical setting), by enabling those who respond to such therapy to transition to more convenient at-home administration of PH10 to maintain the therapeutic benefits of ketamine or esketamine.

About PH10

PH10 is a novel, rapid-acting CNS neuroactive nasal spray administered in microgram doses. PH10 activates nasal chemosensory receptors that, in turn, engage neural circuits that lead to rapid antidepressant effects without psychological side effects, systemic exposure or safety concerns often associated with current antidepressants and ketamine-based therapy (intravenous ketamine or esketamine nasal spray). Based on positive results of an exploratory 30-patient Phase 2a clinical study in MDD in which rapid-onset antidepressant effects were observed without psychological side effects or systemic exposure, VistaGen is preparing for planned Phase 2b clinical development of PH10 in 2020, initially as a new stand-alone treatment for MDD.

About Major Depressive Disorder (MDD)

MDD is a serious neurobiologically-based mood disorder, affecting approximately 16 million adults in the U.S., according to the NIMH. Individuals diagnosed with MDD exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities, for more than a two-week period, as well as impaired social, occupational, educational or other important functioning which has a negative impact on their quality of life. Globally, MDD affects nearly 300 million people of all ages and is the leading cause of disability worldwide.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders with high unmet need. VistaGen's pipeline includes three CNS drug candidates, AV-101, PH10 and PH94B. 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 PH10 and AV-101 for MDD, 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 PH10, AV-101 or our other drug candidates, (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, 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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