

May 27, 2020



VistaGen and Nuformix Announce Agreement to Develop Novel Patentable Cocrystalline Forms of AV-101 for Treatment of Multiple CNS Conditions

Novel Cocrystal Form of AV-101 Administered with Probenecid May Have Superior Delivery, an Enhanced Therapeutic Profile and Additional Intellectual Property Protection

SOUTH SAN FRANCISCO, Calif., May 27, 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 Nuformix plc (LSE: NFX.L), a pharmaceutical development company focused on unlocking the therapeutic potential and value of known drugs, today announced their agreement to develop novel cocrystal-based formulations of VistaGen's CNS product candidates. Under the terms of the agreement, VistaGen and Nuformix initially will apply Nuformix's proprietary technology platform to develop patentable new crystalline forms of AV-101 that may have superior delivery, an enhanced therapeutic profile and additional intellectual property protection. If successful, VistaGen and Nuformix will consider opportunities to extend the collaboration to other CNS therapeutic candidates with a view to unlocking additional therapeutic and commercial opportunities.



VistaGen®

Therapeutics

"Nuformix has a successful track record of using cocrystal technology to re-engineer the crystalline form of small molecule drugs for their own development and for select partners," said H. Ralph Snodgrass, PhD, VistaGen President and Chief Scientific Officer. "Their team is not only highly experienced, but also scientifically creative. We look forward to a productive collaboration."

"We're very pleased to announce this collaboration with VistaGen and the opportunity to collaborate in CNS therapeutics," said Dan Gooding, PhD, Nuformix Chief Executive Officer. "VistaGen and Nuformix share similar objectives in the development of new therapies and we look forward to making an important contribution to VistaGen's comprehensive AV-101 programme and developing the relationship further."

AV-101 is VistaGen's oral NMDAR (N-methyl-D-aspartate receptor) glycine site antagonist, in development in combination with probenecid, a safe and well-known oral drug used to treat gout and to increase the therapeutic benefit of numerous antibacterial, anticancer and antiviral drugs. Recently reported preclinical data suggest that there is a substantially increased brain concentration of AV-101 prodrug (4-Cl-KYN) and its active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), when given together with probenecid. With its exceptionally few side effects and excellent safety profile in all clinical studies to date, AV-101, together with probenecid, has potential to be a new generation oral treatment for chronic neuropathic pain, epilepsy, levodopa-induced dyskinesia associated with Parkinson's disease therapy, major depressive disorder, and suicidal ideation.

About AV-101

AV-101 (4-Cl-KYN) targets the NMDAR (N-methyl-D-aspartate receptor), an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-chlorokynurenic acid (7-Cl-KYNA), which is a potent and selective full antagonist of the glycine co-agonist site of the NMDAR that inhibits the function of the NMDAR. Unlike ketamine and many other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. In all studies to date, AV-101 has exhibited no dissociative or hallucinogenic psychological side effects or safety concerns similar to those that may be caused by amantadine, esketamine and ketamine. With its

exceptionally few side effects and excellent safety profile, AV-101 has potential to be an oral new generation treatment for multiple large-market CNS indications where current treatments are inadequate to meet high unmet patient needs. The FDA has granted Fast Track designation for development of AV-101 as both a potential [adjunctive treatment for MDD](#) and as a [non-opioid treatment for neuropathic pain](#).

About Cocrystals

Pharmaceutical cocrystals are materials composed of two or more different molecules, usually an active pharmaceutical ingredient together with a "co-former" molecule. Cocrystals can be engineered to enhance the bioavailability, pharmacokinetics, stability and manufacturing of drug products.

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 and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

About Nuformix

Nuformix is a pharmaceutical development company focused on unlocking the therapeutic potential and value of known drugs. Nuformix risk-mitigated development strategy has resulted in a pipeline of discoveries through which it has developed and patented novel forms of approved small molecules. Nuformix is targeting high-value unmet needs via drug repurposing with a lead programme in fibrosis (NXP002). Nuformix plc shares are traded on the London Stock Exchange's Official List under the ticker: NFX. For more information please visit www.nuformix.com.

VistaGen Forward-Looking Statements

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding discovery, development and commercialization of patentable cocrystalline forms of AV-101, either alone or in combination with probenecid, for treatment of CNS diseases and disorders with high unmet need, including chronic neuropathic pain, epilepsy, levodopa-induced dyskinesia associated with Parkinson's disease therapy, major depressive disorder, and suicidal ideation. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of our drug candidates. Each of these statements 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. Those risks include the following: (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 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; (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 the substantial additional capital necessary to support our operations, including our ongoing and/or planned preclinical and/or clinical development studies; and (vii) we may encounter technical and other unexpected hurdles and delays 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.

View original content to download multimedia <http://www.prnewswire.com/news-releases/vistagen-and-nuformix-announce-agreement-to-develop-novel-patentable-cocrystalline-forms-of-av-101-for-treatment-of-multiple-cns-conditions-301065803.html>

SOURCE VistaGen Therapeutics