



# Vivet Therapeutics and Pfizer Inc. Enter into Manufacturing Agreement for Vivet's Investigational Gene Therapy for Wilson Disease

Wednesday, September 23, 2020 - 08:59am

PARIS, France and NEW YORK, N.Y.—September 23, 2020— Vivet Therapeutics (“Vivet”), a privately held gene therapy biotech company dedicated to developing treatments for inherited liver disorders with high unmet medical need, and Pfizer Inc. (NYSE: PFE) announced today that they have entered into a manufacturing agreement, under which Pfizer will provide clinical supply for a Phase 1/2 clinical trial evaluating Vivet’s proprietary, investigational gene therapy, VTX-801, for the potential treatment of Wilson disease, a rare and potentially life-threatening liver disorder. The trial is expected to commence in early 2021. Terms of the agreement were not disclosed.

In March 2019, the companies announced that Pfizer had acquired a minority equity interest in Vivet and secured an exclusive option to acquire all outstanding shares. The companies also announced that they would collaborate on the development of VTX-801, for which an Investigational New Drug (IND) application is planned to be filed with the U.S. Food and Drug Administration (FDA) in 2020.

“The manufacture of potentially transformative gene therapy technologies is an incredibly complex undertaking, and we are hopeful that this key milestone further strengthens our relationship with Pfizer while ensuring the long-term development of VTX-801,” said Jean-Philippe Combal, Co-Founder & CEO of Vivet Therapeutics.

The Phase 1/2 clinical supply for VTX-801 will be manufactured in Pfizer's facility in Chapel Hill, North Carolina. In recent years, Pfizer has made significant investments in the company's gene therapy manufacturing facilities in North Carolina to strengthen its ability to produce both clinical and commercial scale quantities of gene therapies for patients living with rare diseases around the world.

"We are proud of the significant progress made to date in our gene therapy manufacturing capabilities, and this milestone in our relationship with Vivet underscores the importance of our strategic investments in end-to-end gene therapy research and supply, to support the timely delivery of these important new therapies for patients," said Seng Cheng, Chief Scientific Officer, Rare Disease Research Unit, Pfizer.

### **About Vivet Therapeutics**

Vivet Therapeutics is an emerging biotechnology company developing novel gene therapy treatments for rare, inherited metabolic diseases.

Vivet is building a diversified gene therapy pipeline based on novel adeno-associated virus (AAV) technologies developed through its partnerships with, and exclusive licenses from, the Fundación para la Investigación Médica Aplicada (FIMA), a not-for-profit foundation at the Centro de Investigación Médica Aplicada (CIMA), University of Navarra based in Pamplona, Spain.

Vivet's lead program, VTX-801, is a novel investigational gene therapy for Wilson disease which has been granted Orphan Drug Designation (ODD) by the Food and Drug Administration (FDA) and the European Commission (EC). This rare genetic disorder is caused by mutations in the gene encoding the ATP7B protein, which reduces the ability of the liver and other tissues to regulate copper levels causing severe hepatic damages, neurologic symptoms and potentially death.

Vivet's second gene therapy product, VTX-803 for PFIC3, received US and European Orphan Drug Designation in May 2020.

Vivet is supported by international life science investors including Novartis Venture Fund, Roche Venture Fund, HealthCap, Pfizer Inc., Columbus Venture Partners, Ysios Capital, Kurma Partners and Idinvest Partners.

Please visit us on <http://www.vivet-therapeutics.com/> and follow us on Twitter at @Vivet\_tx and LinkedIn.

### **About Pfizer: Breakthroughs That Change Patients' Lives**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.Pfizer.com](http://www.Pfizer.com). In addition, to learn more, please visit us on [www.Pfizer.com](http://www.Pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

#### Pfizer Disclosure Notice

*The information contained in this release is as of September 23, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about a manufacturing agreement between Pfizer and Vivet Therapeutics (Vivet), Vivet's investigational gene therapy, VTX-801, and Pfizer's collaboration with Vivet on the development of VTX-801, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, risks related to the ability to realize the anticipated benefits of the transaction, including the possibility that the expected benefits from the transaction will not be realized or will not be realized in the expected time; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any applications may be filed in any jurisdiction for VTX-801; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether*

*VTX-801 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VTX-801; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com)*