Vivet Therapeutics and Pfizer Inc. Announce FDA Authorization to Proceed with GATEWAY, the Phase 1/2 Study for VTX-801, Vivet's Investigational Gene Therapy for Wilson Disease

PARIS, France and NEW YORK, N.Y.—November 18, 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 the U.S. Food and Drug Administration (FDA) has cleared Vivet's Investigational New Drug (IND) application for the GATEWAY study, a Phase 1/2 clinical trial evaluating Vivet's proprietary, investigational gene therapy vector, VTX-801, for the potential treatment of Wilson disease (WD), a rare and potentially life-threatening liver disorder. The trial is expected to commence in early 2021.

"We are pleased to announce Vivet's first IND clearance by the FDA, which is for our GATEWAY Phase 1/2 study for VTX-801," said Jean-Philippe Combal, CEO and Co-Founder of Vivet. "This is a very important milestone for the Wilson disease community for whom VTX-801 could bring significant potential therapeutic benefit. VTX-801 aims to restore copper homeostasis and the GATEWAY trial will measure relevant biomarkers to evaluate physiological restoration of copper elimination and transport in patients. We look forward to advancing VTX-801 into the clinic in early 2021."

VTX-801 is a novel, investigational rAAV-based gene therapy vector designed to deliver a miniaturized ATP7B transgene encoding, a functional protein that has been shown to restore copper homeostasis, reverse liver pathology and reduce copper accumulation in the brain of a mouse model of Wilson disease. VTX-801's rAAV serotype was selected based on its demonstrated tropism for transducing human liver cells.

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. In September 2020, Vivet and Pfizer announced the signing of an agreement for the manufacture by Pfizer of the VTX-801 vector for the GATEWAY study.

"The FDA clearance of Vivet's IND marks an important milestone for the VTX-801 program, which we believe has the potential to become a transformational therapy for people with Wilson disease," said Seng Cheng, Chief Scientific Officer, Rare Disease Research Unit, Pfizer. "Pfizer has begun manufacturing clinical material for the GATEWAY study and look forward to the study's commencement."

"This IND is a recognition of the expertise of Vivet's research team led by our CSO and Co-Founder, Dr. Gloria González-Aseguinolaza, research collaborations, notably with la Fundación para la Investigación Médica Aplicada (FIMA), and experienced development team. We believe that our global development expertise, together with our collaboration with Pfizer, places us in a strong position to rapidly execute and bring this potentially transformational therapy to patients with high unmet medical needs," added Jean-Philippe Combal.

About GATEWAY - Phase 1/2 Clinical Trial of VTX-801 in Wilson disease

The GATEWAY trial is a multi-center, non-randomized, open-label, Phase 1/2 clinical trial designed to assess the safety, tolerability and pharmacological activity of a single intravenous infusion of VTX-801 in adult patients with Wilson disease, prior to and following background WD therapy withdrawal.

Six leading centers in the United States and Europe are expected to participate in the GATEWAY Phase 1/2 trial. The trial is expected to enroll up to sixteen adult patients with Wilson disease and will evaluate up to three doses of VTX-801. Patients will participate in a pre-dosing observational period and will be administered a prophylactic steroid regimen.

The primary endpoint of the GATEWAY trial is to assess the safety and tolerability of VTX-801 at 52 weeks after a single infusion. Additional endpoints include changes in disease-related biomarkers, including free serum copper and serum ceruloplasmin activity, as well as radiocopper-related parameters and VTX-801 responder status to allow standard-of-care withdrawal.

Vivet Therapeutics expects to enroll the first patient in early 2021.

More details on:

https://clinicaltrials.gov/ct2/show/NCT04537377?term=VIVET&draw=2&rank=1

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 recombinant adeno-associated virus (rAAV) 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 Medica 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 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. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of November 18, 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 Vivet Therapeutics' (Vivet) 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 collaboration, including the possibility that the expected benefits from the collaboration 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 and www.pfizer.com.