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ASIA EDITION

Vyera to Initiate Phase 1 Study of NCE for Toxoplasmosis

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The letter from the FDA gives permission for Vyera to proceed with dosing human subjects in its Phase 1 SADstudy of VYR-006.

Vyera Pharmaceuticals, LLC has announced that it plans to initiate a Phase 1 single ascending dose (SAD) study of VYR-006, a novel dihydrofolate reductase (DHFR) inhibitor which Vyera discovered and is developing for the treatment of toxoplasmosis. The United States Food and Drug Administration (FDA), the government agency that oversees pharmaceuticals and clinical research in the U.S., issued a Study May Proceed letter to Vyera on November 6, 2018, in response to Vyera's submission of an Investigational New Drug Application (IND). The letter from the FDA gives permission for Vyera to proceed with dosing human subjects in its Phase 1 SAD study of VYR-006. Vyera intends to begin a multiple ascending dose study pending satisfactory completion of the SAD study.

Vyera's Head of Research and Development, Dr. Nicholas Pelliccione commented, "Receiving permission from the FDA to proceed with our Phase 1 study of VYR-006 is a great step forward for us. Vyera's mission from the beginning has been to create and develop new therapies for diseases that are rare and often neglected. The discovery of VYR-006 by our own in-house scientists and now proceeding to a clinical program is the initial fulfillment of that mission for the company and hopefully may lead to a new therapy for patients who require treatment for this serious condition."

Vyera's drug discovery program identified VYR-006 through its efforts to create a toxoplasmosis treatment that will be more potent and better tolerated than existing options. Toxoplasmosis, a parasitic infection caused by *Toxoplasma gondii (T. gondii)* , is a leading cause of death attributed to food-borne illness in the United States. Toxoplasmosis is caused by the parasite *Toxoplasma gondii,* and more than 40 million people in the United States may be infected by the parasite, which can persist in the body for a lifetime. A toxoplasma infection could cause serious health problems ranging from flu-like symptoms to causing damage to the brain, eyes and other organs, particularly in pregnant women or individuals who have compromised immune systems. Persons who are ill with toxoplasmosis can be treated with a combination of drugs, and in certain patients it may be necessary to continue medication for the rest of their lives.

The Centres for Disease Control and Prevention (CDC) identified toxoplasmosis as one of five neglected parasitic infections targeted for public health action. VYR-006 is a new chemical entity and a potent DHFR inhibitor, which has demonstrated efficacy in cell-based and animal models of acute toxoplasmosis. VYR-006, currently a capsule, is expected to be explored further for safety and efficacy in upcoming clinical investigations that are anticipated to take place in the U.S. and a variety of other countries around the world.