

Myasthenia gravis: CuraVac launches phase 1b study in patients

Parallel phase 2b studies planned in Europe and USA in 2017

Wilmington, Delaware, USA, February 9, 2016 – CuraVac Inc, a clinical-stage biopharmaceutical company developing a new class of immunotherapies against autoimmune diseases, today announces that it has launched a phase 1b study of its lead program, CV-MG01. CV-MG01 is an immunotherapy developed for the treatment and potential cure of myasthenia gravis, a debilitating autoimmune disease. Patient enrollment has begun. A European phase 2b study, to be conducted by the Myasterix consortium, financed by the European Union, is programmed for 2017. Subject to further funding, the company also plans to launch a parallel phase 2b study in the USA.

CV-MG01 received orphan designation from the FDA's Office of Orphan Products Development in 2011 and from the European Medicines Agency (EMA) in 2009. CV-MG01 is an entirely novel immunotherapy that is being assessed for the treatment and potential cure of myasthenia gravis. It is a combination of two synthetic peptides that have demonstrated in preclinical studies the ability to cure myasthenia gravis. The technology behind CV-MG01 is applicable to a range of other autoimmune diseases such as multiple sclerosis (MS), lupus (SLE), Graves' and Hashimoto diseases and Guillain-Barre Syndrome (GBS-CIDP).

Myasthenia gravis is a rare autoimmune disease with no known cure. It is characterized by muscular fatigue leading to extreme weakness. The disease attacks muscles controlling voluntary movement and can affect the eyes, swallowing and breathing. Typical early symptoms include eyelid drooping and double vision. Speech can also be affected. Current treatment options are not curative and have significant side effects.

The study, coordinated by the Belgian operating subsidiary, CuraVac Europe S.A., is a randomized, placebo-controlled, double-blind study that will enroll approximately 30 adult patients across one placebo and two active groups. Each patient in the active groups will receive three subcutaneous doses of CV-MG01 and will be monitored initially for up to five months. The primary study endpoint is safety. Secondary endpoints include immunogenicity and efficacy assessed by clinical signs and biomarkers. The study is being conducted at the University Hospital of Antwerp (UZA), Belgium, in collaboration with the Leiden University Medical Centre (LUMC) in The Netherlands. Results are expected in late 2016.

"We are particularly pleased as this is the first time that a specific immunotherapy for the treatment of myasthenia gravis has been studied clinically," said Stephane Huberty, MD, chief executive officer at CuraVac. "Having now successfully initiated a first-in-man study and having pre-financed our follow-on European study, thanks to the European Union, we are now planning to conduct parallel clinical work in the US," he continued. "We also wish to explore the applicability of our technology to the treatment of other autoimmune diseases."

About Myasthenia Gravis (MG)

MG is characterized by muscular fatigue leading to extreme weakness. The fatigue is caused by the loss of ability to convert nerve impulses into muscle contraction. Underlying these symptoms is an autoimmune disease in which the patient's own antibodies (autoantibodies) attack receptors at the nerve/muscle interface. The disease affects muscles controlling voluntary movement, including those associated with actions such as swallowing and breathing; usually progressing from mild to more severe symptoms. Between 200,000 and 250,000 people have been diagnosed with MG in Europe, the USA and Japan alone. These figures may underestimate the true prevalence. At present, there is no cure for MG. Current treatment options are often life-long and typical medications include corticosteroids and immunosuppressants; both of which induce significant side effects. Plasma exchange and intravenous immunoglobulins are used during acute phases of the disease. These treatments are very expensive and have many severe side effects. Many MG patients undergo thymectomy (surgical removal of the thymus) in the hope of lessening the severity of the autoimmune reaction.

About CuraVac, Inc.

CuraVac, Inc. is a clinical-stage biopharmaceutical company focused on the development of a new class of immunotherapies for treating autoimmune and inflammatory diseases including myasthenia gravis (MG), multiple sclerosis (MS) and other diseases. The company's independent advisory board includes Jean-Paul Prieels, PhD, previously head of research at GSK Biologicals, Didier Hoch, PhD, previously chairman of Sanofi Pasteur MSD, Bruce Forrest, M.D., previously senior vice president at Wyeth Pharmaceuticals, and Prof. Marc de Baets, M.D., PhD, clinical neurologist and MG expert at Maastricht University Hospital. CuraVac is the scientific coordinator and the commercial partner of the Myasterix consortium, which receives funding under the European Union's Seventh Framework Program.

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