



Press Release

## **MYASTERIX Phase 1b clinical study is launched to test a therapeutic vaccine for Myasthenia Gravis.**

**Rixensart, Belgium, December 23, 2015** - The MYASTERIX consortium has launched the Phase 1b clinical trial of an innovative antigen specific treatment that aims to provide significant and lasting improvement of myasthenia gravis (MG). The study will evaluate the safety, immunogenicity, and also explore the efficacy of a therapeutic vaccine candidate (coded CV-MG01) with designated orphan drug status in the USA and Europe by the FDA and the EMA. CV-MG01 comprises two synthetic complementary peptides conjugated to a carrier protein.

Myasthenia Gravis (MG) is an acquired autoimmune disease that typically begins with ocular symptoms such as double vision and drooping eyelids, and then progresses to general weakness in the majority of the patients, involving facial muscles, speaking and swallowing, and limb and respiratory muscles. Symptomatic treatment, corticosteroid treatment, immunosuppressive drugs, and improved intensive care facilities have significantly improved treatment outcome, but still a large proportion of patients depend on long-term immunosuppressive treatment, with potentially severe side-effects.

The MYASTERIX Phase 1b study (EudraCT 2015-002880-41) will assess the safety, immunogenicity and explore the efficacy of CV-MG01 administered in three subcutaneous injections at weeks 1, 4 and 12. The study is randomized, double-blind, placebo-controlled and includes a dose escalation. The study will be carried out on 32 MG patients and comprises 2 parts, an active part that lasts 5 months and an observational part that lasts 2 years to assess long-term treatment effects.

Dr. Stephane Huberty, Managing director of CuraVac, says: *"We are delighted we can now start this long-awaited clinical trial for our MG therapeutic vaccine. We hope that this trial will go beyond showing that we can significantly improve the life of MG patients and that it will open the door for a new class of therapies applicable to other autoimmune diseases."*

The MYASTERIX trial is sponsored by CuraVac Europe, a company based in Belgium and conducted at the Antwerp University Hospital (Belgium) in collaboration with the Leiden University Medical Center (the Netherlands), Aepodia (Belgium & France), piCHEM (Austria) and Inserm Transfert (France). This trial is a major milestone for the MYASTERIX project funded by the European Union's Seventh Framework Programme.

More information on the clinical trial can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website with the reference number NCT02609022 or by searching the keywords "Myasterix" or "CuraVac".

### **About the MYASTERIX consortium:**

The MYASTERIX consortium was formed on CuraVac's initiative in 2012 and is supported by the European Union through a grant of €5.9 million under the Seventh Framework Programme for research, technological development and demonstration under Grant Agreement number 602420. The

consortium aims to advance a therapeutic vaccine candidate - CV-MG01 with orphan drug status - for the autoimmune disease Myasthenia Gravis (MG) to human proof-of-concept studies. The project involves the manufacturing of the human formulation of CV-MG01 for clinical trials and the conduct of a Phase 1b study followed by a Phase 2b in MG patients. Partners of the MYASTERIX consortium are:

- CuraVac Europe, a biotech company based in Belgium [www.curavac.com](http://www.curavac.com)
- The Leiden University Medical Center in the Netherlands [www.lumc.nl](http://www.lumc.nl)
- The Antwerp University Hospital in Belgium [www.uza.be](http://www.uza.be)
- piCHEM, a contract manufacturing organization in Austria [www.pichem.at](http://www.pichem.at)
- Aepodia, a clinical research company based in Belgium and France [www.aepodia.com](http://www.aepodia.com)
- Inserm Transfert, a technology transfer office in France [www.inserm-transfert.fr](http://www.inserm-transfert.fr)

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