Clinical safety, immunogenicity and efficacy of a therapeutic vaccine that combines peptides mimicking antigen receptors on autoimmune B and T cells associated with myasthenia gravis

Fact Sheet

Project Information

**Myasterix**

Grant agreement ID: 602420

Status
Closed project

Start date 1 October 2013
End date 30 September 2018

Funded under
FP7-HEALTH

Overall budget
€ 7 538 399.15

EU contribution
€ 5 900 720

Coordinated by
INSERM TRANSFERT SA
France

Objective

The MYASTERIX project will advance a therapeutic vaccine candidate (designated orphan drug) indicated for the autoimmune disease myasthenia gravis (MG) to clinical proof of concept studies. MG is caused by T cell dependent antibodies that bind to and deplete acetylcholine receptors (AChR) at neuromuscular junctions causing muscle weakness by interfering with neuromuscular transmission and junction architecture. The vaccine candidate comprises two synthetic peptides designed to generate antibodies that bind to autoantibodies and T-cell receptors associated with MG. These peptides prevented or improved muscle fatigue in a rat model of MG and increased the remission rate to 75% in pet dogs (compared to 17% natural remission rate in historical controls). In both models, administration of the peptides resulted in reduced titres of anti-AChR antibodies and lower numbers of...
peptides resulted in reduced titres of anti-AChR antibodies and lower numbers of anti-AChR T-cells, based on the induction of antibodies that bound to the corresponding B and T cell antigen receptors. These results suggest that similar antigen receptor mimetic vaccination approaches could drive autoimmune diseases like MG into long-term remission.

The objectives of the project are to manufacture toxicology and clinical batches of the vaccine human formulation based on already developed and tested standard operating procedures, to carry out stability and regulatory toxicity testing of the GMP product, to conduct phase I and subsequently phase II clinical trials to demonstrate safety, tolerability and proof of mechanism of action/concept of the therapeutic vaccine.

The impact on MG patients will be to offer a targeted therapeutic approach requiring only three injections, bringing significant and lasting improvement or even a cure. MG is a model for many autoimmune diseases and the concept of targeted therapeutic vaccines could lead to a new class of drugs for the treatment of autoimmune diseases more generally, with a significant impact on innovation, competitiveness and society.

Field of science
/agricultural sciences/animal and dairy science/pets
/medical and health sciences/basic medicine/toxicology
/medical and health sciences/basic medicine/pharmacology and pharmacy/pharmaceutical drug/vaccines

Programme(s)

Topic(s)

Call for proposal
FP7-HEALTH-2013-INNOVATION-1

Funding Scheme
CP-FP - Small or medium-scale focused research project

Coordinator

INSERM TRANSFERT SA
Participants (5)

**CURAVAC EUROPE SPRL**

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Activity type

Private for-profit entities
(excluding Higher or Secondary Education Establishments)

Website

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Administrative Contact

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**piCHEM Forschungs und Entwicklungsgmbh**

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Activity type

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Website

Contact the organisation

Administrative Contact

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Activity type
Private for-profit entities excluding Higher or Secondary Education Establishments

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Activity type
Research Organisations

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