



PRESS RELEASE

Clinical trial of rheumatism gene therapy gets approval

ArthroGen announces approval for Phase Ib study with gene therapy ART-I02 in patients with rheumatoid arthritis.

Amsterdam, the Netherlands - February 16 2017. Today, biopharmaceutical company ArthroGen announced the approval for the ART-I02 gene therapy clinical phase Ib study in patients with rheumatoid arthritis. The clinical trial will focus on rheumatoid arthritis patients who, despite multiple treatments with existing medicines, still suffer from inflamed joints. The new approach is unique in that it aims to stimulate the local production of an anti-inflammatory protein within the inflamed joint by means of a single treatment. A virus is used to deliver a piece of genetic material into the joint, which will then produce its own anti-inflammatory protein in the inflamed area, only when needed. It is expected that one single injection will have a long-lasting effect. This initial trial will be used to examine safety and the first signs of effects. The study will be executed by the Centre for Human Drug Research (CHDR) in Leiden in close collaboration with University Medical Centers in the Netherlands.

Everyday millions of people worldwide have to endure the pain and discomfort of rheumatoid arthritis. Despite the fact that huge progress has been made in recent years, due to the advent of several new medicines, a significant proportion of patients still suffer from persistent symptoms. This indicates how substantial the impact of rheumatoid arthritis is on both individual patients and society in general. A new one-time gene therapy treatment with a long-term effect, like ART-I02 might bring about a positive change in the current situation. Gene therapy includes treatments which are designed to repair a genetic defect or to deliver a piece of genetic material by means of a virus, which will then have a healing effect.

ART-I02, a recombinant adeno-associated virus (rAAV) serotype 2/5 vector is genetically designed to encode human interferon- β (hIFN- β). Transcription of the hIFN- β mRNA is controlled by an inflammation-inducible promoter, the nuclear factor (NF)- κ B-responsive promoter, resulting in the expression of the therapeutic protein during flares of rheumatoid arthritis.

The trial will be conducted by the Centre for Human Drug Research (CHDR) in cooperation with University Medical Centers in the Netherlands. The trial will start recruitment in the first quarter of 2017 with the aim of presenting its results by the end of 2018. If this first trial proves to be successful a subsequent trial will follow which will look in greater depth at the effects of the treatment and will contribute further towards a new treatment for rheumatoid arthritis and other diseases.

The engine behind this new development is the Amsterdam-based biotech company ArthroGen which was founded in 2005 at the Academic Medical Center (AMC) of the University of Amsterdam. Researchers at the AMC made discoveries aimed at offering new alternatives to patients using safe, local treatment of rheumatoid arthritis by means of a single injection. In the past 12 years ArthroGen has developed a series of products based on these initial findings, with the continuous support of an investor from Dubai, the AMC and an Innovation Credit from the Ministry of Economic Affairs. ART-I02 is the first which has now reached the clinical stage.

For further information (not to be published):

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