

Press Release

MediGene Initiates Clinical Formulation Study of RhuDex[®] for the Oral Treatment of Autoimmune Diseases

- **Innovative study design permits fast and cost-efficient execution; results expected midyear 2012**
- **Objective is to determine an oral formulation for chronic treatment**

Martinsried/Munich, January 25, 2012. The biotech company [MediGene AG](#) (Frankfurt, Prime Standard) continues clinical development of its drug candidate [RhuDex[®]](#) by initiating a clinical formulation study. The trial objective is to develop an optimized oral formulation of the active substance suitable for the treatment of chronic diseases. The results of this formulation study are expected midyear 2012.

Dr. Frank Mathias, CEO of MediGene AG, comments: "The initiation of this formulation study is an important step in the development of this innovative drug candidate. We developed an optimized formulation concept which, in the case of successful clinical testing, will add a significant competitive advantage to RhuDex[®]."

Previous preliminary formulations of RhuDex[®] permitted initial clinical trials of the drug candidate. For the long-term development and subsequent marketability of the product, MediGene seeks an improved oral formulation and dosage form of RhuDex[®] to facilitate a therapeutically ideal release of the active ingredient, as well as a patient-friendly dosing regimen.

During the formulation study, a single dose of RhuDex[®] will be administered orally to up to twelve volunteers. Based on the innovative RapidFACT[™] (Rapid Formulation Development and Clinical Testing) study design, variants of formulations can be tested over a short period because the trial medication is produced immediately prior to dosing. This approach facilitates a fast and cost-efficient execution of the trial.

RhuDex[®]: MediGene is developing RhuDex[®] as an oral, disease-modifying drug for the treatment of autoimmune diseases, such as rheumatoid arthritis. RhuDex[®] is a CD80 antagonist that blocks the undesired activation and proliferation of T cells and thus has an immunomodulating and anti-inflammatory effect. This drug candidate can be classified with the group of "Disease-Modifying Antirheumatic Drugs" (DMARDs). In a phase IIa trial in 29 patients, RhuDex[®] demonstrated indications of biological activity relevant for the treatment of rheumatoid arthritis.

Rheumatoid arthritis: rheumatoid arthritis is the most common inflammatory arthropathy worldwide. More than 0.5 - 1% of the world's population is affected by this chronic disease, which leads to pain, deformity, restricted mobility, and often stiffening of the joints. The body's own connective tissue (e.g., articular cartilage) is attacked and damaged by the individual's immune system. For this reason, rheumatoid arthritis is considered to be an autoimmune disease.



This press release contains forward-looking statements representing the opinion of MediGene as of the date of this release. The actual results achieved by MediGene may differ significantly from the forward-looking statements made herein. MediGene is not bound to update any of these forward-looking statements. MediGene[®] and RhuDex[®] are registered trademarks of MediGene AG. These trademarks may be owned or licensed in select locations only.

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MediGene AG is a publicly listed (Frankfurt: MDG, prime standard) biotechnology company headquartered in Martinsried/Munich, Germany. MediGene is the first German biotech company to have revenues from marketed products. It has various drug candidates in clinical development and possesses innovative platform technologies. MediGene focuses on clinical research and development of novel drugs against cancer and autoimmune diseases.

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