

## MediGene Achieves Positive Results with RhuDex<sup>®</sup> in Clinical Phase IIa Trial

**Martinsried/Munich June 24, 2008.** MediGene AG (Frankfurt, Prime Standard: MDG) has achieved its objectives in a clinical phase IIa trial of the drug candidate RhuDex<sup>®</sup> for the treatment of rheumatoid arthritis. Apart from positive safety data and the good adsorption after oral administration, first indication of biological activity of RhuDex<sup>®</sup> was observed. The data regarding pharmacokinetics (behaviour and distribution of the drug in the body) and bioavailability (concentration of the active ingredient in the blood after drug administration) obtained in the trial will, among other aspects, form the basis of the design of a comprehensive phase II trial of RhuDex<sup>®</sup> which is scheduled for initiation in 2009, as announced earlier. A new pharmaceutical form of RhuDex<sup>®</sup> as a tablet has been developed in the meantime and shall provide additional treatment facilitation for the patients.

The present two-week placebo-controlled pilot trial was conducted with patients suffering from rheumatoid arthritis, with simultaneous treatment with the standard methotrexate. Apart from the tolerability of RhuDex<sup>®</sup>, the oral availability of the drug was also examined. After an increase of the plasma level after treatment with 100 and 200 mgs of RhuDex<sup>®</sup>, a saturation of the plasma concentration was reached with 400 mgs of RhuDex<sup>®</sup>. Therewith the primary trial objective was achieved. The substance RhuDex<sup>®</sup> showed good tolerability in all 29 patients, and in all dosages administered. Another important result is the fact that no interaction between RhuDex<sup>®</sup> and the standard drug methotrexate was observed.

In the planned phase II trial with the new formulation of RhuDex<sup>®</sup> as a tablet the patients are to be treated over a period of three months, and efficacy data for RhuDex<sup>®</sup> are to be collected.

Dr. Peter Heinrich, Chief Executive Officer of MediGene AG, considers the great potential of MediGene's research and development activities to be confirmed by these new data: "Having obtained very convincing results with EndoTAG<sup>TM</sup>1 in a clinical phase II, we are now very happy about these promising data from the trial of RhuDex<sup>®</sup>. With the new pharmaceutical form as a tablet, which represents a major progress in both the development of RhuDex<sup>®</sup> and in the treatment of rheumatoid arthritis, we are going to conduct a large-scale trial to test this highly attractive substance for its efficacy."

**RhuDex<sup>®</sup>:** RhuDex<sup>®</sup> is being developed as a disease-modifying antirheumatic drug (DMARD), a successful group of drugs. As the first orally administered and specifically effective DMARD, RhuDex<sup>®</sup> promises a clear competitive advantage. RhuDex<sup>®</sup> targets at stopping T-cell activation by specifically blocking the very well defined target protein CD80, thus inhibiting the release of cytokines which stimulate inflammation. Thus the disease-causing mechanism is to be specifically stopped. MediGene estimates the maximum annual sales potential of RhuDex<sup>®</sup> at more than one billion Euros.

**Rheumatoid arthritis:** rheumatoid arthritis is the most common inflammatory arthropathy. More than 1% of the world population is affected by this chronic, systemic disease of the connective tissue which leads to pain, deformity, restricted mobility, and often to stiffening of the joints affected.

*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 statements made herein. MediGene is not bound to update any of these forward-looking statements. EndoTAG<sup>TM</sup>-1 and MediGene<sup>®</sup> are trademarks of MediGene AG, RhuDex<sup>®</sup> is a trademark of MediGene Ltd. These trademarks may be owned or licensed in select locations only.*



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**MediGene AG** is a publicly quoted (Frankfurt, Prime Standard: MDG) biotechnology company located in Martinsried/Munich, Germany, with subsidiaries in Oxford, UK and San Diego, USA. MediGene is the first German biotech company to have drugs on the market, which are being distributed by partner companies. Another drug candidate has just received official recommendation for marketing authorization by the EMEA. MediGene has several drug candidates in clinical development, including two products which each have an annual sales potential of more than one billion Euros per year. MediGene also has projects in research and pre-clinical development and possesses innovative platform technologies for the development of active ingredients. MediGene concentrates on researching, developing and commercializing novel drugs in three therapeutic areas: cancer, autoimmune diseases, and skin diseases.

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