

Ad hoc announcement

## **RhuDex™ Clinical Development to Continue Following Feedback from Regulatory Authorities**

**Martinsried/Munich, October 5, 2009.** MediGene AG (Frankfurt: MDG, Prime Standard, TecDAX) received feedback from the UK MHRA (Medicines and Healthcare products Regulatory Agency) regarding the in-vitro studies conducted with the drug candidate RhuDex™ for the treatment of rheumatoid arthritis. These in-vitro studies examined potential effects of RhuDex™ on the vascular system or any arteriosclerotic blood vessels. Since these tests did not suggest any negative effects of RhuDex™, the MHRA agreed to a continuation of the drug candidate's clinical development, without requesting any further in vitro or ex vivo data.

MediGene is planning to resume the Phase I clinical development for RhuDex™, thus laying the necessary foundation for a clinical Phase II trial in patients. As the extended plan for clinical development is drafted, MediGene will coordinate with the competent regulatory authorities.

Following a successful Phase IIa trial in 29 patients during the first six months of 2008, MediGene conducted a clinical Phase I trial of a new tablet formulation of RhuDex™. This trial was put on hold in July 2008, following the death of a trial participant from myocardial infarction. The autopsy, revealed severe impairment of cardiac function of the volunteer deemed to be present prior to admission to the trial, as well as other scientific findings. MediGene considered any causal correlation between the death of the patient and the administration of RhuDex™ to be unlikely, but for safety reasons the Company proceeded to test RhuDex™ in a series of further laboratory studies in coordination with the MHRA.

*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.*

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