**Press Release**

# Medigene signs licence agreement with Falk Pharma for RhuDex® in hepatology and gastroenterology

- **Dr. Falk Pharma GmbH to fund all costs for development and commercialization of RhuDex® in the indication areas hepatology and gastroenterology**
- **Medigene eligible for an upfront payment, milestone payments plus double-digit royalties**
- **Falk Pharma will initially concentrate on development in primary biliary cirrhosis (PBC)**
- **Medigene retains RhuDex® rights for rheumatoid arthritis and other autoimmune diseases**

**Martinsried/Munich, 18 March 2014.** Biotechnology company, Medigene AG (MDG1, Frankfurt, Prime Standard) has signed an exclusive global licence agreement with the company Dr. Falk Pharma GmbH (Falk Pharma) for the development and commercialization of its drug candidate RhuDex® for indications in hepatology and gastroenterology. Falk Pharma will assume responsibility and all costs relating to the clinical development and marketing of RhuDex® in these therapeutic areas. Medigene will receive an upfront payment and future milestone payments from Falk Pharma, plus double-digit RhuDex® royalties. Falk Pharma will initially concentrate on development in primary biliary cirrhosis (PBC). Medigene retains the rights for RhuDex® in the indication areas rheumatoid arthritis, psoriasis and other autoimmune diseases.

**Dr. Frank Mathias, CEO of Medigene AG**, explained: "In Falk Pharma, we have found an ideal partner for RhuDex®. Falk Pharma has already successfully developed and launched several drugs to treat diseases of the liver and biliary tract. After the transforming acquisition of Trianta Immunotherapies GmbH, this partnership for RhuDex® represents another major step in the implementation of our strategy for sustainable growth."

**Ursula Falk, Managing Director of Dr. Falk Pharma GmbH,** commented: "RhuDex® possesses an innovative mode of action and complements our existing development and commercial portfolio. We will use our years of expertise in this field to further develop this attractive product candidate to a successful drug."

**Peter Llewellyn-Davies, CFO of Medigene AG**, commented: "With this agreement we continue to implement our licensing plans for the advanced product candidates. Yet we will retain the major part of our rights to RhuDex®, e.g. for the treatment of rheumatoid arthritis or psoriasis. This license agreement facilitates the further clinical development of RhuDex® and also contributes to the financing of our immunotherapy programs recently acquired which will open up new partnering and financing opportunities."

Confidentiality was agreed on financial details of the deal. Medigene will provide the company's financial and operational guidance with the annual financial and operations report and conference call on 27 March 2014.

**About Falk Pharma:** Dr. Falk Pharma GmbH is headquartered in Freiburg, southern Germany, and maintains a global presence. It is a market leader in gastroenterology and hepatology. The company specialises in the development and sale of drugs for certain indication areas, such as PBC (primary biliary cirrhosis). Alongside Germany, the drugs – most of which are prescription drugs – are marketed in over 65 other countries. In many cases, commercialisation is based on cooperation with local partners and in some cases, via the company's own sales subsidiaries.

The development department of Dr. Falk Pharma GmbH relies on employees with many years of experience in galenicals, preclinical and clinical development. Current development activities focus on new substances for treating chronic inflammatory and other gastrointestinal diseases as well as diseases of the liver, biliary tract and oesophagus, and the further development of Falk products that are already approved in the market. For further information, please visit www.drfalkpharma.de.

**About RhuDex:** RhuDex® is being developed by Medigene as a first-in-class modifying agent for the oral treatment of autoimmune diseases. Autoimmune diseases are characterized by the inappropriate activation of immune reactions against autologous tissue. Activation and proliferation of such auto-reactive T-cells and the resultant release of inflammatory mediators plays a major role in the pathogenesis and course of auto-immune diseases. Pivotal in this process is the interaction of the CD28 protein receptor on the surface of T-cells with the CD80 protein on the surface of other immune cells. RhuDex® has the ability to bind to CD80, thus preventing interaction with CD28. By doing so, an important signaling pathway of T-cell activation is blocked. The safety and tolerability of RhuDex® has been demonstrated in a number of phase I clinical trials. In the indication rheumatoid arthritis Medigene successfully concluded a phase IIa pilot trial.

**About primary biliary cirrhosis (PBC):** The autoimmune disease PBC is a chronic liver disease that initially affects the bile ducts. The bile ducts are progressively destroyed by inflammatory processes, causing biliary stasis and build-up of bile in the liver. Liver tissue is destroyed and replaced by connective tissue, liver cirrhosis develops. As in rheumatoid arthritis, the activation of T cells via a CD28-CD80 interaction has been described as involved in the pathogenesis of PBC, a process that is to be inhibited by RhuDex® treatment. PBC belongs to the orphan diseases, i.e. a group of rare and severe medical conditions. Under certain circumstances, the development, approval and marketing of drugs for the treatment of orphan diseases are supported by public subsidies.

**Medigene AG** is a publicly listed (Frankfurt: MDG1, prime standard) biotechnology company headquartered in Martinsried near Munich, Germany. Medigene concentrates on clinical research and development of novel drugs against cancer and autoimmune diseases and, following the acquisition of Trianta Immunotherapies GmbH, focuses on personalized T cell immunotherapies. Medigene is the first German biotech company to have revenues from a marketed product, Veregen®, which is distributed by commercial partners companies. Medigene has various drug candidates in clinical trials, EndoTAG®-1 and RhuDex® and DC vaccine, and it is developing highly innovative treatment platforms. Medigene's wholly-owned subsidiary, Trianta, is developing next generation antigen-tailored dendritic cell (DC) vaccines, T cell receptor (TCR)-based adoptive cell therapy and T cell-targeted antibodies (TABs).For more information, please visit www.medigene.com.



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