

**Press Release**

**MediGene: Veregen<sup>®</sup> Marketing Approval Process Initiated  
for 17 Additional European Countries**

**Decision on Marketing Approvals Expected End of Q1 2012**

**Martinsried/Munich, December 12, 2011.** [MediGene AG](#) (Frankfurt, Prime Standard) announces that the regulatory authorities of seventeen additional European countries accepted the marketing authorization applications for [Veregen<sup>®</sup>](#) ointment using the mutual recognition procedure. This means that the review procedure has started. The decision for marketing approval in Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden is expected by the end of the first quarter of 2012. Assuming a positive decision, the individual countries will grant marketing approvals for Veregen<sup>®</sup> in the course of the subsequent national phase of the approval procedure.

Veregen<sup>®</sup> is currently available in the United States, German, and Austrian markets. In Spain, the drug was granted marketing approval and market launch is expected in 2012. Veregen<sup>®</sup>'s German marketing approval serves as the basis for the mutual recognition procedure. The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) will make its evaluation reports on Veregen<sup>®</sup>'s quality, efficacy, and safety available to the participating countries. The Institute will also coordinate the process between MediGene and the other countries.

MediGene has entered into several marketing partnerships for Veregen<sup>®</sup>, including Fougera (formerly Nycomed) for the United States; Abbott for Germany, Austria, and Switzerland; Laboratoires Expanscience for France; and with a number of other partners across Europe, America, and Asia. MediGene is planning to continue this global licensing strategy.

**Veregen<sup>®</sup>:** Veregen<sup>®</sup> (previously Polyphenon E<sup>®</sup> ointment), a topical treatment of external genital warts, contains a concentrate of catechins with a complex defined composition extracted from green tea leaves. MediGene acquired the basic rights to the active ingredient in Veregen<sup>®</sup> from Epitome Pharmaceuticals, Inc. in 1999, and was solely responsible for the drug's successful preclinical and clinical development, as well as the approval process. Sin catechins 15 % ointment (Veregen<sup>®</sup>) is now also recommended as a treatment option in the US Department of Health and Human Services Center for Disease Control and Prevention's the Sexually Transmitted Diseases Treatment Guidelines 2010 for the treatment of genital warts.

*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<sup>®</sup> and Veregen<sup>®</sup> are registered trademarks of MediGene AG. Polyphenon E<sup>®</sup> is a trademark of Mitsui Norin Co., Ltd. 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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