



MEDIGENE RECEIVES ORPHAN DRUG STATUS FOR ITS BRAIN CANCER DRUG CANDIDATE G207

Seven Years Marketing Exclusivity after FDA Approval for G207 – Tax Benefits on Clinical Research and Development Costs – Clinical Protocol Assistance from the Office of Orphan Products Development

Martinsried/San Diego, May 8, 2002. The German-American biopharmaceutical company MediGene (NMarkt: MDG) announced today that the Office of Orphan Products Development (OOPD) of the United States Food and Drug Administration (FDA) has granted orphan drug designation for its drug candidate G207 for the treatment of malignant glioma, one of the most aggressive brain tumors in man. Orphan drug designation allows MediGene exclusive marketing rights for G207 in the US for seven years following marketing approval by the FDA. The designation also enables MediGene to apply for clinical research funding, tax credits on clinical research and development expenses, potential waiver of user fees associated with filing of the marketing application as well as for assistance from the OOPD in guiding the drug through the regulatory approval process.

„We are extremely gratified that the FDA has granted our brain cancer product orphan drug status. G207, a novel oncolytic, is in clinical development for treating the most common and aggressive primary brain tumor. The designation will help in the development process of G207 and in significantly strengthening its market position in the future,“ says Dr. Johanna Holldack, Chief Operating Officer of MediGene.

The Orphan Drug Act was established by Congress to encourage research and development of new therapies for rare diseases and conditions, i.e. those that affect less than 200,000 patients in the U.S. The drug candidate, G207, is being developed for the treatment of malignant glioma, an indication with an annual incidence of approximately 30,000 patients in Europe and the USA combined. Current treatment methods, such as surgery, aggressive chemotherapy and radiotherapy, are often not effective and tend to cause considerable side effects.

G207 is a modified Herpes Simplex Virus (HSV) and part of MediGene`s novel HSV technology for treating different types of tumors. The oncolytic HSV technology is based on the ability of genetically modified herpes simplex viruses to infect and destroy a diversity of tumour cells without harming the healthy cells or causing severe inflammatory reactions. The fact that replicating HSV can be inactivated with existing, licensed antiviral drugs increases the safety of this technology. Based on excellent phase 1/2 tolerability and safety results MediGene is currently testing the efficacy of G207 in a phase 1b/2 clinical trial.

This press release contains forward-looking statements that involve risks and uncertainties. The forward-looking statements contained herein represent the judgement of MediGene as of the date of this release. These forward-looking statements are no guarantee for future performance, and the forward-looking events discussed in this press release may not occur. MediGene disclaims any intent or obligation to update any of these forward-looking statements.

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MediGene AG

MediGene AG is a publicly quoted (Nemax50), internationally orientated biopharmaceutical company with headquarters in Martinsried, Germany and a wholly owned subsidiary MediGene, Inc in San Diego, USA. MediGene has the most extensive and most mature drug development pipeline in Germany and is one of the leading European biopharmaceutical companies. Besides five broad platform technologies, the company has 7 therapeutic products in clinical development and registration. The core competence lies in the research and development of innovative and high-efficient approaches for the treatment of various, so far incurable cardiac and cancer diseases, and therefore on indications of high medical and economic interest.

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