**Press Release**

**MediGene Announces Investigator Initiated Trial of EndoTAG®-1 and Presentation of Final Phase II Overall Survival Data at the San Antonio Breast Cancer Symposium**

- Investigator initiated trial of EndoTAG®-1 in combination with paclitaxel for hormone-receptor-positive, HER2-negative breast cancer.

- Final overall survival data from the phase II clinical trial of EndoTAG®-1 in triple-negative breast cancer (TNBC) will be presented for the first time at the San Antonio Breast Cancer Symposium on December 8, 2011.

**Martinsried/Munich, November 8, 2011. MediGene AG (MDG, Frankfurt, Prime Standard) announced today that Prof. Dr. Ahmad Awada, principal investigator in the EndoTAG®-1 phase II trial in TNBC, will conduct an investigator initiated trial (IIT) of EndoTAG®-1 in hormone-receptor-positive, HER2-negative breast cancer, which is an additional potential indication for the drug. The trial is entitled “An open-label phase II trial evaluating the efficacy and safety of neoadjuvant EndoTAG®-1 in combination with paclitaxel in patients with HER2-negative high-risk breast cancer.” MediGene will provide EndoTAG®-1 for the study.**

Prof. Dr. Ahmad Awada, Head of the Medical Oncology Clinic at Jules Bordet Institute in Brussels, Belgium, commented: “The experience gathered with EndoTAG®-1 in TNBC has encouraged me to initiate a trial to investigate this interesting drug candidate in a type of breast cancer that affects 70 – 85% of all breast cancer patients. Previous findings indicate that EndoTAG®-1 in combination with paclitaxel might represent a novel treatment option for those patients suffering from hormone-receptor-positive breast cancer.”

During the IIT, 20 patients diagnosed with HER2-negative breast cancer will be treated with EndoTAG®-1 (22 mg/m²) in combination with paclitaxel (70 mg/m²) once-weekly over a period of twelve weeks as neoadjuvant therapy prior to surgery. Treatment of the patients with EndoTAG®-1 is expected to be completed in the second half of 2012. Following EndoTAG®-1 therapy, the patients will be treated with standard chemotherapy and, subsequently, surgery. Endpoints of the trial include reduction in linear tumour size as measured by MRI as well as pathological complete response (pCR) at the time of surgery. The trial results are expected in 2013.

Separately, and for the first time, Prof. Dr. Ahmad Awada will present median overall survival data from the phase II clinical trial of EndoTAG®-1 in TNBC at the San Antonio Breast Cancer Symposium in San Antonio, Texas, USA. The presentation, entitled “Final Results of a Controlled, Randomized 3-Arm Phase II Trial of EndoTAG®-1, a Cationic Liposomal Formulation of Paclitaxel Targeting Tumor Endothelial Cells, in Advanced Triple-Negative Breast Cancer (TNBC)” will take place on December 8, 2011, from 5:00 pm – 7:00 pm (CST). 140 patients participated in this trial.

**EndoTAG®-1:** Clinical drug candidate EndoTAG®-1 is a novel composition of paclitaxel combined with neutral and positive lipids. It attacks activated endothelial cells that are needed for the formation of new tumor blood vessels. The drug candidate selectively attaches itself to newly developed, negatively charged tumor blood vessels, thus attacking only the blood supply of the tumor and not the blood supply of healthy tissue. EndoTAG®-1 is expected to prevent the formation of new vessels and suppress further tumor growth.
MediGene assumes that due to the genetic stability of endothelial cells compared to tumor cells, EndoTAG®-1 can be used for the treatment of those tumors that have already developed a resistance to conventional paclitaxel therapy.

MediGene successfully completed two phase II clinical trials with EndoTAG®-1 in pancreatic cancer and triple-negative breast cancer, and has developed a more cost-effective manufacturing process. European and US authorities have granted orphan drug designation for EndoTAG®-1. This status affords certain benefits in the development, approval process, and, under certain circumstances, the commercialization of the drug.

**HER2-negative breast cancer:** According to recent estimates, about 193,000 newly diagnosed cases of breast cancer and 41,000 deaths associated with it occurred in 2009 in the USA alone. Breast cancer is by far the most common type of cancer in women, accounting for 27% of cancer diagnoses. In 70 - 85% of all breast cancer cases, the tumor cells do not express any HER2 receptors, and are therefore referred to as HER2-negative. This type of breast cancer cannot be treated with therapies targeted at the HER2 receptor, such as monoclonal antibodies.

**Triple-negative breast cancer (TNBC):** The triple-negative breast cancer represents a subtype of HER2-negative breast cancers. Triple-negative breast tumors are malignant and do not show any HER2 receptors or hormone receptors for estrogen or progesterone. About 15% of all breast cancer cases rank among this group. There are very few treatment options available, since conventional anti-hormonal treatments or treatments targeting HER2 are not appropriate. In case of relapse following initial surgery, the only remaining treatment option is chemotherapy, which also provides only a limited number of suitable therapeutics for this type of cancer.

*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® and EndoTAG® are registered trademarks of MediGene AG. 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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