

Press Release

MediGene Presents Overall Survival Data from a Phase II Trial of EndoTAG[®]-1 in Triple-Negative Breast Cancer (TNBC)

- **Positive efficacy trend of EndoTAG[®]-1/Paclitaxel combination therapy confirmed**
- **Subgroup analysis reveals encouraging overall survival data with EndoTAG[®]-1 plus paclitaxel combination therapy**

Martinsried/Munich, December 9, 2011. [MediGene AG](#) announces median overall survival data from its phase II trial of [EndoTAG[®]-1](#) for the treatment of triple-negative breast cancer ([TNBC](#)), which was presented at the San Antonio Breast Cancer Symposium in San Antonio, USA. The secondary endpoint data confirm the positive efficacy trend of EndoTAG[®]-1 in combination therapy with standard weekly paclitaxel, which was previously reported by the primary endpoint data (progression-free survival rate at 16 weeks). Furthermore, an additional analysis of a subgroup of patients not predefined in the study protocol (119 of 140 patients: ECOG 0/1, first-line therapy for advanced cancer) showed encouraging overall survival data with EndoTAG[®]-1/paclitaxel combination therapy. The data were presented by Prof. Dr. Ahmad Awada, principal investigator of this trial and Head of the Medical Oncology Clinic at Jules Bordet Institute in Brussels, Belgium.

Trial design: 140 patients diagnosed with TNBC participated in the phase II clinical trial. Patients were randomized to three groups and received either EndoTAG[®]-1 in combination with weekly paclitaxel (55 patients) or EndoTAG[®]-1 monotherapy (57 patients). The third group (28 patients) only received weekly paclitaxel. The patients treated with combination therapy received 22 mg/m² EndoTAG[®]-1 plus 70 mg/m² paclitaxel once per week. EndoTAG[®]-1 monotherapy was administered twice per week, in a dosage of 44 mg/m² per treatment. The paclitaxel monotherapy consisted of a once weekly 90 mg/m² dose. The clinical trial was conducted in more than 30 centers in several European countries and in India. The study was not powered for intergroup comparisons.

Overall survival data: Median overall survival time (as at reference date "visit week 41" of the last patient treated) for those 133 patients with TNBC status confirmed by central lab was 13.0 months in the EndoTAG[®]-1/paclitaxel combination therapy arm (51 patients), 11.9 months in the EndoTAG[®]-1 monotherapy arm (57 patients), and 10.1 months in the paclitaxel monotherapy arm (25 patients). Further data analysis of this group was done for those 124 patients treated per protocol. Median overall survival in this group was 15.1 months in the EndoTAG[®]-1 combination therapy arm (48 patients), 12.5 months in the EndoTAG[®]-1 monotherapy arm (52 patients), and 8.9 months in the paclitaxel monotherapy arm (24 patients). Additionally, MediGene analyzed a subgroup of patients that was not predefined in the study protocol. This included patients with centrally confirmed TNBC status, ECOG performance status of 0/1 at the start of the clinical trial and who received first-line treatment after tumor relapse (119 patients). Median overall survival in this group was 17.8 months in the EndoTAG[®]-1 combination therapy arm (45 patients), 11.7 months in the EndoTAG[®]-1 monotherapy arm (50 patients), and 10.1 months in the paclitaxel monotherapy arm (24 patients).

Prof. Dr. Ahmad Awada, principal investigator in this trial, commented: "The overall survival data collected in this trial suggested a promising anti-tumoral effect of EndoTAG[®]-1, especially in the combination therapy with weekly paclitaxel. In particular, the overall survival data of the subgroup of patients analyzed is very encouraging to support a phase III program. If the results prove to be true in a phase III clinical trial, EndoTAG[®]-1 in combination with paclitaxel, may represent an efficacious and safe treatment option."

Data regarding the primary endpoint of the trial (progression-free survival rate at week 16), the secondary endpoints progression-free survival rate, clinical benefit rate, and best overall response, as well as safety and tolerability of EndoTAG[®]-1 have previously been published and are available at http://www.medigene.de/presse_en/endoTAGTNBC.

EndoTAG[®]-1: The 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 believes 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 has 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.

As recently announced, Prof. Ahmad Awada is about to start an Investigator Initiated Trial (phase II neoadjuvant study) with EndoTAG[®]-1/paclitaxel combination in HER2-negative breast cancer.

Triple-negative breast cancer (TNBC): 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.

- ends -

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.

Contact MediGene AG

Julia Hofmann, Kerstin Langlotz
Investor & Public Relations
Tel.: +49 - 89 - 85 65 - 33 01
Fax: +49 - 89 - 85 65 - 29 20
Email: investor@medigene.com