

Press Release

## MediGene publishes first, preliminary results obtained in a phase II clinical trial of EndoTAG™-1 for the treatment of triple receptor-negative breast cancer

**Martinsried/Munich, May 6, 2010.** The biotech company MediGene AG (Frankfurt, Prime Standard, TecDAX) announces first preliminary results from its Phase II clinical trial of the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer. The trial in 140 patients was conducted to show efficacy of EndoTAG™-1 against this extremely difficult to treat cancer type, and to further investigate the safety of the drug candidate. The primary endpoint was a progression-free survival rate at 16 weeks of at least 30% of EndoTAG™-1 monotherapy treated patients, and at least 30% of EndoTAG™-1 plus paclitaxel combination treated patients respectively. At the same time the bottom line of the 95% confidence interval also had to be above 30%.

Data available at this time reveal a progression-free survival rate of 59.1% after treatment with EndoTAG™-1 combination therapy, and further data are currently being evaluated and will be published within the next few weeks. Upon conclusion of this analysis, an overall trial evaluation will therefore be possible. The data published today are based on a centralised image evaluation of the trial results regarding progression-free survival.

**Trial design:** The trial recruited 140 patients diagnosed with triple receptor-negative breast cancer. These patients were randomized into three groups, receiving either treatment with EndoTAG™-1 in combination with the cytostatic drug paclitaxel (55 patients) or EndoTAG™-1 monotherapy (57 patients). The third group (28 patients) was treated with paclitaxel alone. The number of patients that could be considered for this centralised image evaluation was 44 (EndoTAG™-1 combination therapy), 38 (EndoTAG™-1 monotherapy), and 25 (paclitaxel monotherapy). The patients treated with combination therapy received 22 mg/m<sup>2</sup> EndoTAG™-1 once a week plus 70 mg/m<sup>2</sup> paclitaxel. EndoTAG™-1 monotherapy was administered twice every week, in a dosage of 44 mg/m<sup>2</sup> each. The paclitaxel monotherapy consisted of one weekly 90 mg/m<sup>2</sup> dose. The clinical trial was conducted in over 30 centers across several European countries and in India.

**Trial results:** The group of patients treated with EndoTAG™-1 and paclitaxel combination therapy showed a progression-free survival rate after 16 weeks of treatment of 59.1% (95% confidence interval: 43.2% - 73.7%). The progression-free survival rate of the group with EndoTAG™-1 monotherapy was 34.2% (18,6 % - 51,4 %). In the group that received paclitaxel monotherapy, the progression-free survival rate was 48%. (27,8 % - 68,7%).

**Dr. Frank Mathias, Chief Executive Officer of MediGene AG, commented:** "We are delighted to show that patients treated with EndoTAG™-1 combination therapy could benefit in this way from our drug candidate. Subject to further data analysis which will permit a more thorough evaluation, the achievement of the primary endpoint in this trial with EndoTAG™-1 combination therapy represents a positive result of our clinical trial."

**Triple receptor-negative breast cancer:** According to recent estimates<sup>1</sup>, in 2009 about 193,000 newly diagnosed cases of breast cancer and 41,000 deaths associated with it occurred in the USA alone. Breast cancer is by far the most common type of cancer in women,

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<sup>1</sup> Source: American Cancer Society, 2009

accounting for 27% of cancer diagnoses. Malignant breast tumors that do not possess estrogen, progesterone or HER2/NEU receptors are called triple receptor-negative breast cancer. About 15% of all breast cancers belong to this subgroup.<sup>2</sup> Patients suffering from this type of breast cancer have a significantly poorer prognosis, and there are very few treatments available since conventional anti-hormonal treatments or treatments targeting HER2 are not appropriate. In case of recurrence following initial surgery, the only remaining treatment option is chemotherapy, and this provides only a limited number of suitable therapeutics for this type of cancer.

**EndoTAG™-1:** EndoTAG™-1 adds an innovative variant to the validated therapeutic approach of anti-angiogenesis. The drug candidate attaches itself selectively to newly developed negatively charged tumor blood vessels, thus attacking only these blood vessels and not those in healthy tissue. Concurrently, EndoTAG™-1 prevents the formation of new vessels, thus suppressing further tumor growth. EndoTAG™-1 is a combination of positively charged liposomes with the therapeutic substance paclitaxel embedded therein. MediGene believes that such an approach on genetically stable endothelial cells will not lead to resistance formation.

EndoTAG™-1 is MediGene's first product candidate derived from the EndoTAG™ platform technology. MediGene obtained positive results with EndoTAG™-1 in a controlled phase II clinical trial in pancreatic cancer. In Europe and the USA EndoTAG™-1 has been granted orphan drug designation which potentially provides both cost and timeline benefits in the drug development process.

*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 statements made herein. MediGene is not bound to update any of these forward-looking statements. MediGene, EndoTAG™ and EndoTAG™-1 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, Prime Standard: MDG, TecDax) biotechnology company located in Martinsried/Munich, Germany, with subsidiaries in Oxford, UK and San Diego, USA. MediGene is the first German biotech company to have drugs on the market which are distributed by partner companies. It has several drug candidates in clinical development and possesses innovative platform technologies. MediGene focuses on clinical research and development of novel drugs with focus on oncology.

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<sup>2</sup> Source: Cleator S, Heller W, Coombes R Ch. Triple-negative breast cancer: therapeutic options. Lancet Oncol 2007; 8:235-44