

Ad hoc 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/m² EndoTAG™-1 once a week plus 70 mg/m² paclitaxel. EndoTAG™-1 monotherapy was administered twice every week, in a dosage of 44 mg/m² each. The paclitaxel monotherapy consisted of one weekly 90 mg/m² 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%).

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.

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Contact MediGene AG

E-mail: investor@medigene.com

Fax: ++49 - 89 - 85 65 - 2920

Julia Hofmann / Dr. Nadja Wolf, Public Relations, Tel.: ++49 - 89 - 85 65 - 3324

Dr. Georg Dönges, Investor Relations, Tel.: ++49 - 89 - 85 65 - 2946

