

## MediGene Achieves Excellent Efficacy Data of EndoTAG™-1 in Clinical Phase II Trial in Pancreatic Carcinoma

- Treatment with EndoTAG™-1 leads to substantially extended survival time compared to standard therapy in a controlled trial in 200 patients
- Novel mode of action of selectively destroying tumor vascularization has been demonstrated
- MediGene intends to present data at upcoming clinical conference

**Martinsried/Munich, March 17, 2008.** MediGene AG (Frankfurt, Prime Standard: MDG) achieved excellent efficacy data in a clinical phase II trial of EndoTAG™-1 in the indication pancreatic carcinoma. The trial in 200 patients showed substantially extended survival time of those patients treated with EndoTAG™-1 in combination with the standard drug gemcitabine, compared to those receiving only gemcitabine. The survival time of the patients treated improved coinciding with increased dosage of EndoTAG™-1, and particularly with increased duration of treatment.

The trial was conducted in three groups receiving different dosages, and one control group (only gemcitabine). The median survival time of the group treated with the highest dosage of EndoTAG™-1 increased by 30 % compared to the control group. After six months of treatment, the survival rate in this dosage group was also still about 30 % higher than in the control group. Patients who received treatment with EndoTAG™-1 repeatedly over a longer period of time showed even a substantially better survival time and survival rates. The positive safety profile of EndoTAG™-1 shown in the interim analysis was maintained as well as its positive effect on the patients' quality of life. MediGene intends to present data at an upcoming clinical conference. The detailed data evaluation will be published in the fourth quarter of 2008.

The European Commission granted the orphan drug designation for EndoTAG™-1 in the indication pancreatic cancer, ensuring EU market exclusivity for the drug for a period of ten years following marketing authorization.

**Prof. Matthias Löhr**, Professor of Gastroenterology & Hepatology at Karolinska Institutet, Stockholm, and Head of Molecular Gastroenterology, German Cancer Research Center (DKFZ) Heidelberg and the study's principal investigator, comments: "The treatment of pancreatic cancer represents a tremendous challenge in oncology, due to its aggressive progression and the dissatisfying therapy options. In the past there has been very little progress in the therapy of this tumor. The results achieved in this trial of EndoTAG™-1 are very impressive. The data suggest that, upon successful further development, EndoTAG™-1 may provide a marked improvement in the therapy of pancreatic cancer."

**Dr. Ulrich Delvos**, Executive Board Member for Research & Development of MediGene AG, comments: "The efficacy data presented today represent a breakthrough in MediGene's EndoTAG™ development. The excellent trial results effectively confirm the mode of action: by destroying the tumor blood vessels, the cancer cells are virtually "starved out". This means that EndoTAG™-1 could in principle be suited for the treatment of all solid, highly vascularized types of tumors. The EndoTAG™ platform technology also offers therapeutic options for other diseases associated with pathological vascularization. The trial results also give us optimism with regard to our ongoing clinical phase II trial of EndoTAG™-1 in hormone-resistant breast cancer."

"We are very glad about the proof of concept of EndoTAG™ in pancreatic cancer, which represents one of the most difficult indications in oncology", comments **Dr. Peter Heinrich**, CEO of MediGene. "Survival is the essential factor by which cancer drugs are judged. This



treatment option should bring benefits to patients with a variety of cancers and opens the company a potential for a billion market."

**Design and objectives of the phase II trial in the indication pancreatic cancer:** The patients enrolled in the trial suffered from inoperable, advanced, or metastasized pancreatic carcinoma. They were randomly assigned to one of four groups. In three of these groups, the patients received various doses of EndoTAG™-1 twice a week for a period of seven weeks. Once a week, EndoTAG™-1 was administered in combination with gemcitabine. In the control group, the patients received monotherapy with only gemcitabine once a week. In the second stage of the trial, there was an opportunity to continue the treatment with EndoTAG™-1 if the tumor showed a response. The trial investigated safety, tolerability, and efficacy trends of the various doses of EndoTAG™-1 in combination with gemcitabine. In addition to the data reported today regarding the median survival time and the six-month survival rate, there will be a final evaluation of the twelve-month survival rate, the tumor response to treatment, and the influence of the therapy on the patients' quality of life.

**Pancreatic carcinoma:** With approximately 32,000 incidences annually in the US, and a similar number of deaths, pancreatic carcinoma ranks fourth among the tumor-related causes of death. Only 5 to 25 % of the newly diagnosed patients are still operable at the time of diagnosis. The average survival time of the patients is as low as six to seven months. Approximately 19 % of the patients survive one year, and the five-year survival rate is only 4 %. Therefore there is a tremendous unmet need for novel therapeutic options for this aggressive types of cancer. At present, gemcitabine is the most common drug for the treatment of pancreatic carcinoma.

**EndoTAG™-1:** EndoTAG™-1 consists of positively charged lipid complexes which transport the dissolved cytostatic drug paclitaxel systematically to the negatively charged endothelial cells of the newly formed tumor blood vessels. The drug is expected to attack the tumor blood vessels, simultaneously preventing the growth of new blood vessels. This should significantly reduce the nutrient supply of the tumor tissue, and stops further tumor growth. During the phase II trial in the indication pancreatic cancer the cytostatic drug Gemcitabine, which is directly targeted at the remaining tumor cells, was administered in combination with EndoTAG™-1. In addition to the phase II trial in pancreatic cancer reported in this press release, MediGene is currently conducting a phase II trial of EndoTAG™-1 for the treatment of hormone-resistant breast cancer, the results of which are expected in 2009. On the basis of MediGene's EndoTAG™ platform technology, the company is also investigating other therapeutic approaches using EndoTAG™.

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

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**MediGene AG** is a publicly quoted (Frankfurt, Prime Standard: MDG) 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. In 2008, the company plans to start its own sales activities in select European countries. MediGene's drug pipeline includes several products in clinical development, among them two drug candidates with an estimated revenue potential of more than one billion Euro. In addition, MediGene is active in various research projects and possesses platform technologies for developing active compounds.

**Contact MediGene AG**

Email: [investor@medigene.com](mailto:investor@medigene.com), Fax:++49 - 89 – 85 65- 2920

Julia Hofmann/Dr. Georg Dönges, Public Relations, Tel.: ++49 - 89 - 85 65 - 3317



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