

Press Release

MediGene reports additional phase II results of EndoTAG™-1 for the treatment of triple receptor-negative breast cancer

Clinical trial objective achieved - data confirm positive efficacy trend of EndoTAG™-1 combination therapy

Martinsried/Munich, June 24, 2010. The biotechnology company, MediGene AG (Frankfurt, Prime Standard, MDG, TecDAX) announces additional phase II clinical trial results of the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer. The extensive data analysis of the three-arm trial conducted in 140 patients confirms a positive efficacy trend of EndoTAG™-1 in combination with paclitaxel for the treatment of this difficult to treat type of cancer. The objective of the trial was achieved, and the initial conclusion of the preliminary data published on May 6, 2010 was verified.

The primary endpoint was achieved with EndoTAG™-1 combination therapy. In addition, the analysis of the secondary endpoints (median progression-free survival, non-progression rate, safety, and tolerability) shows further positive results for EndoTAG™-1 combination therapy.

Trial design

The trial recruited 140 patients diagnosed with triple receptor-negative breast cancer. These patients were randomized into three treatment groups, receiving either EndoTAG™-1 in combination with the cytotoxic drug, paclitaxel (55 patients), or EndoTAG™-1 monotherapy (57 patients). The third group (28 patients) was treated with paclitaxel alone. 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 across several European countries and India. According to the trial protocol, the trial results are based on centralized data analysis. The patient numbers whose data were eligible for the central analysis are shown in the following results.

Trial results

The trial objective of evaluating efficacy of EndoTAG™-1 was achieved by the combination therapy with Paclitaxel.

Primary endpoint: The primary endpoint was a progression-free survival rate of the patients treated with either EndoTAG™-1 monotherapy or EndoTAG™-1 plus paclitaxel combination of at least 30% after 16 weeks of treatment. At the same time, the 95% confidence interval, which provides information about the potential error rate, also had to be above 30%. The group of patients treated with EndoTAG™-1 and paclitaxel combination therapy showed a progression-free survival rate of 59% (26 of 44 patients). The group treated with EndoTAG™-1 monotherapy achieved a rate of 34% (13/38). For the group treated with paclitaxel monotherapy, this rate was 48% (12/25). Regarding the set confidence interval, the primary trial endpoint was met by the EndoTAG™-1 combination therapy arm only.

Secondary endpoints: Median progression-free survival time during the trial was 4.2 months in the EndoTAG™-1 combination therapy arm (52 patients), 3.4 months in the EndoTAG™-1 monotherapy arm (48), and 3.7 months in the paclitaxel monotherapy arm (25). The rate of patients whose tumors had not progressed further (clinical benefit rate) in treatment week 16

was 59% in the EndoTAG™-1 combination therapy arm (26/44 patients), 34% in the EndoTAG™-1 monotherapy arm (13/38), and 50% in the paclitaxel monotherapy arm (12/24). In 76% of the patients in the EndoTAG™-1 combination therapy arm (38/50), the tumor was either stable or regressive at a certain point in time during the treatment period (best overall response). The corresponding rate was 58% for the EndoTAG™-1 monotherapy arm (26/45), and 58% for the paclitaxel monotherapy arm (14/24). Safety and tolerability profile of EndoTAG™-1 was confirmed during the trial. The combination of EndoTAG™-1 with paclitaxel did not lead to additional toxicity.

Professor Dr. Ahmad Awada, Head of the Medical Oncology Clinic, Department of Medicine, Institut Jules Bordet, Brussels, and principal investigator of the trial, commented: "These are promising results for a disease that is as difficult to treat as triple receptor-negative breast cancer. Since the trial demonstrated a clinical benefit combining EndoTAG™-1 with paclitaxel, I am confident that this therapy may represent a novel treatment option in the future."

Dr. Frank Mathias, Chief Executive Officer of MediGene AG, commented: "Following the positive phase II clinical results obtained in pancreatic cancer indication, this trial conducted in another very difficult to treat type of cancer also shows clear indication of efficacy of EndoTAG™-1. The data represent further clinical evidence of the therapeutic principle (proof-of-concept) of EndoTAG™-1 combination therapies for indications with high medical need."

About triple receptor-negative breast cancer: According to recent estimates by the American Cancer Society, approximately 193,000 newly diagnosed cases of breast cancer and 41,000 deaths associated with it occurred in the USA in 2009. Breast cancer is by far the most common type of cancer in women, accounting for 27% of cancer diagnoses. Malignant breast tumors that do not possess estrogen, progesterone or HER2 receptors are called "triple receptor-negative" breast cancer. About 15% of all breast cancers belong to this subgroup.¹ 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 also provides only a limited number of suitable therapeutics for this type of cancer.

About EndoTAG™-1: EndoTAG™-1 represents an innovative therapeutic approach that unfolds its effect by both a targeted antivascular (against newly formed tumor blood vessels), and an anti-tumoral (directed against the tumor) mechanism. 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, which is expected to suppress further tumor growth. EndoTAG™-1 is a combination of positively charged liposomes with the therapeutic substance paclitaxel embedded therein.

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 provides both cost and timeline benefits in the drug development process.

Analyst conference call and webcast: An analyst conference call in English will take place today at 2.30 p.m. (CEST), and will be webcast live. The webcast and synchronized

¹ Source: Cleator S, Heller W, Coombes R Ch. Triple-negative breast cancer: therapeutic options. *Lancet Oncol* 2007; 8:235-44

presentation slides can be accessed at www.medigene.com. A recording of the live presentation will also be available thereafter.

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 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 emphasis on oncology.

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