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Press Release

ANTISENSE PHARMA Announces Results From Phase I/II Study For AP 12009 In Malignant Brain Tumors

REGENSBURG, GERMANY - June 4, 2002. Data from the first Phase I/II trial of Antisense Pharma's AP 12009 in patients with recurrent high-grade glioma were presented at the 38th Annual Meeting of the American Society of Clinical Oncology (ASCO) and report excellent safety and tolerability. Within a 64fold escalation of the initial dose no dose-limiting side effects or maximum tolerated dose were observed. The primary endpoint was to determine safety and tolerability. Surpassing this objective, first efficacy data were also obtained. Thus far, 6 out of 18 patients show a stabilization or response. The study was conducted by the Departments of Neurology and Neurosurgery, University of Regensburg, and the Department of Neurosurgery, University of Kiel.

The clinical Phase I/II study was designed with the primary objective of determining the maximum tolerated dose in patients with malignant glioma who had failed other therapies. All patients were treated with a single course of AP 12009 via an intra-tumoral catheter to bypass the blood brain barrier. Both operable and inoperable patients had been enrolled. All of them had received at least one previous chemotherapy, usually temozolamide. The overall median survival time with AP 12009 following temozolamide is longer compared to the literature data for temozolamide alone.

"Based on the results seen in this Phase I/II study, we are excited to investigate AP 12009 in international trials which will utilize the same route and schedule of administration but will provide multiple cycles of AP 12009 to each patient" said Dr. Gerhard Stauder, Chief Scientific Officer at Antisense Pharma. "The Data Safety Monitoring Board (DSMB) confirmed that the safety profile of the study drug is excellent and no safety concerns have been reported." The DSMB is an independent body of oncologists and neurologists responsible for evaluating patient safety and ensuring the integrity of the trial.

High-grade glioma is the most malignant brain tumor in man with more than 50,000 patients in the territories USA, Europe and Japan diagnosed in the WHO grade III (anaplastic astrocytoma) or grade IV (glioblastoma). These patients need new treatment options as their survival rates are poor, and chemotherapy and radiation therapy have significant and often permanent side effects. Patients with progressive tumor growth have an impaired immune function. The key way for tumors to escape immune surveillance is by overexpressing the strongest immunosuppressor known, TGF-beta (transforming growth factor). High-grade gliomas strongly overexpress this factor.

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AP 12009 is a phosphorothioate antisense oligonucleotide and represents a selective TGF-beta2 inhibitor. It works by targeting the overexpression of TGF-beta2 mRNA and blocking the signaling pathways within the cell that are implicated in the growth and survival of cancer cells. This target mode of action is different from cytotoxic chemotherapies and small molecule or peptide protein inhibitors. The key advantages of AP 12009 are reversing the TGF-beta2 induced immunoblockade, reactivating the immune system to fight the tumor, and at the same time inhibiting tumor cell growth and migration. As AP 12009 targets mRNA, it is not expected to induce mutagenesis resulting in drug resistance.

"We are excited about the clinical data showing not only safety but also efficacy data on AP 12009." said Dr. Karl Schlingensiepen, Chief Executive Officer at Antisense Pharma. "This is a great step forward towards bringing this novel compound to the patients and to thus improve clinical prognosis and quality of life. The results also strongly endorse our development program for AP 12009 in other solid tumors."

Antisense Pharma GmbH is a German biotech business engaged in the research, development, and marketing of prescription pharmaceuticals for highly unmet medical needs. Antisense Pharma is exploiting its unique expertise in the antisense technology to develop novel human anticancer drugs.

For more information, please visit our web site at www.antisense-pharma.com

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