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Press Release

AP 12009 to Start Phase IIb Study In Recurrent Malignant Brain Tumors after Excellent Phase I/II Results

REGENSBURG, GERMANY - April 10, 2003. Antisense Pharma GmbH announces the start of a Phase IIb clinical trial with its AP 12009 targeting TGF-beta2. This multi-national, open-label randomized controlled parallel-group study will comprehend more than 20 trial sites in Western and Eastern Europe, India and Israel and is expected to recruit 150 patients with recurrent high-grade glioma.

AP 12009 has been developed to block the excess expression of transforming growth factor-beta2 (TGF-beta2), which is known to correlate with bad prognosis in high-grade glioma and other tumors. TGF-beta overexpression leads to progression from a localized tumor to metastatic cancer.

The data have shown excellent safety and tolerability. Within a more than 100-fold escalation of the initial dose the substance showed an excellent safety profile and no drug related lab changes were observed.

The primary endpoint of the study was to determine safety and tolerability. Surpassing this objective, efficacy data were obtained. Patients having received the widely used chemotherapy temozolomide (TMZ) before AP 12009 were compared to data from TMZ registration studies: the median overall survival was 106.4 weeks as compared to 42 weeks with TMZ alone in patients with anaplastic astrocytoma, and 46.1 weeks as compared to 32 weeks in glioma patients. These results were achieved in spite of the terminal stage of the enrolled patients, their mostly large tumor sizes and following only one course of AP 12009 therapy, two patients having received two courses.

A patient having shown a complete response is still alive more than two years after the treatment. Moreover, the complete remission of the tumors in the other hemisphere and at more distant sites than that of the original lesion and which were not directly exposed to AP 12009 infusion is a proof of concept of the reactivation of the immune response after downregulation of TGF-beta2 by AP 12009.

"To our knowledge, this complete remission in all tumor sites after local treatment is exceptional and has not been described before", comments Dr. Stauder, CSO at Antisense Pharma GmbH.

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All patients of the first trial were treated with 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 temozolomide.

High-grade glioma is the most malignant brain tumor in man. These patients need new treatment options as their survival rates are still 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 TGF-beta (transforming growth factor), the strongest immunosuppressor known. The antisense AP 12009 targets this central factor of cancer cell proliferation and survival.

"We are excited about the clinical data supporting our therapeutic concept. Based on these data the international Phase II trial with an active control arm in leading clinical centers has just been initiated." said Dr. Karl-Hermann Schlingensiepen, Chief Executive Officer at Antisense Pharma GmbH. "The results also strongly endorse our development program for AP 12009 in other solid tumors."

Antisense Pharma GmbH is a German biotech company engaged in the research, development, and marketing of antisense pharmaceuticals to overcome highly unmet needs by treating especially malignant, advanced cancer.

For information, please visit the website at www.antisense-pharma.com

This press release contains forward-looking statements with respect to the future business of Antisense Pharma GmbH. By their nature, forward-looking statements and forecasts involve risks and uncertainties because they relate to events and depend on circumstances that could occur in the future. There are a number of factors that could cause actual results and developments to differ materially. Antisense Pharma GmbH disclaims any intent or obligation to update any of these forward-looking statements.