



We are not aware of any published Alzheimer's disease study in which a drug has achieved statistically significant benefits of the breadth, size and duration of those seen in our first pivotal clinical trial of Dimebon.

In January 2008, the FDA informed us that this trial can be used as one of the two pivotal studies required to support the approval of Dimebon to treat mild-to-moderate Alzheimer's disease, as long as a significant portion of the sites in our confirmatory pivotal Phase 3 trial are located in the United States. However, as is typically the case at this stage of the regulatory review process, the FDA has not yet performed an in-depth review of our preclinical and clinical data, so its views remain subject to change.

We plan to begin our second, confirmatory pivotal Phase 3 Alzheimer's disease trial in the second quarter of 2008.

Dimebon Being Studied for Treatment of Huntington's Disease

Huntington's disease is a progressive, neurodegenerative disease that affects 30,000 patients in the U.S. with another 150,000 at risk. It is caused by the death of specific brain cells and is characterized by the gradual development of involuntary muscle movements, progressive deterioration of cognitive processes and memory (dementia), and severe behavioral disturbances. No drugs are approved by the U.S. Food and Drug Administration (FDA) to treat this uniformly fatal genetic disorder. Dimebon has been shown in preclinical studies to protect neurons against the neurotoxic human huntingtin protein, which is the cause of Huntington's disease.

As a result, we are currently evaluating Dimebon in an ongoing Phase 2 trial in collaboration with the Huntington Study Group, a network of clinical trial investigators from academic and research institutions throughout the United States, Canada, Europe and Australia. The trial is a three-month randomized, placebo-controlled, double-blind evaluation of the safety and preliminary efficacy of Dimebon in approximately 90 Huntington's disease patients. The primary efficacy endpoint is the Unified Huntington's Disease Rating Scale (UHDRS). Results are expected in the second quarter of 2008.

MDV3100 for Prostate Cancer

We are conducting an open-label, Phase 1-2 clinical trial of MDV3100 in patients with hormone-refractory prostate cancer. The trial is being conducted at several clinical sites in the United States, including Memorial Sloan-Kettering Cancer Center in New York. The study endpoints include safety, tolerability, pharmacokinetics, effects on serum prostate-specific antigen (PSA) levels and disease progression.

In November 2007, we announced early PSA data from the two lowest dose groups in this clinical trial. MDV3100 reduced serum PSA levels in all six patients enrolled in both dose groups in a dose-dependent manner. In the lowest dose group, after two months of treatment, PSA levels declined 45 percent to 66 percent. PSA levels in the second lowest dose group declined 75 percent to 89 percent after the first month of treatment. MDV3100 has been well-tolerated to date in both dose groups. No dose-limiting toxicities have been identified and dose-escalation continues in the study. These PSA reductions are early data from a small number of patients, and we do not yet know whether they will be confirmed at the end of the study or if PSA reductions will correlate with an improvement in overall survival, which generally is required for approval. Nonetheless, we believe these early data provide encouragement regarding MDV3100's potential as a treatment for hormone-refractory prostate cancer.

The original design of this trial provided for expansion of a single dose group to 20 patients once a maximum tolerated dose was established. However, based on the early tolerability and PSA data, we have obtained approval to expand additional dose groups. Enrollment in these expansion groups, which include both patients who are chemotherapy naïve and patients who have failed chemotherapy, is underway. Given these expansions, we expect to enroll approximately 100 patients in this trial. We expect to complete the study in 2008. If the results are positive, we plan to seek FDA agreement in 2008 to enter pivotal Phase 3 registration studies.

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Key Facts

Ticker Symbol
NASDAQ: MDVN

Shares Outstanding
28.8 million

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