

Sponsor Presentation (Merck): Vioxx (Rofecoxib)

Introduction: Peter Kim MD

JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

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Highlights

- **3-STUDY CV SAFETY PLAN:** After cardiovascular safety concerns with Vioxx emerged, Merck deliberated with its outside advisers and developed in discussions with FDA a plan to evaluate cardiovascular safety in three large placebo-controlled trials.
- **VIOXX 2004 WITHDRAWAL:** Following preliminary data from one of these trials, Merck voluntarily withdrew Vioxx.
- **WITHDRAWAL COULD BE RE-EVALUATED:** The decision to withdraw Vioxx was based on “the science available at that time”. However, since that time, “new cardiovascular safety data for other COX-2 inhibitors have become available” and will be discussed and interpreted at this meeting.

Presentation Text

Mr. Chairman, members of the advisory committee and FDA and ladies and gentlemen, my name is Peter Kim and I am President of Merck Research Laboratories. My colleagues and I welcome the opportunity to present information at this advisory committee meeting, and I would like to begin with just a few introductory comments.

As you will hear, to determine both its risks and its benefits, Merck extensively

studied Vioxx before seeking regulatory approval to market it, and we continued to conduct clinical trials after the FDA approved Vioxx. As Merck continued to monitor the cardiovascular safety of Vioxx, we recognized the value and interest in obtaining additional cardiovascular safety data on this medicine. After deliberations with numerous outside advisors, Merck developed and discussed with FDA a plan to prospectively analyze

cardiovascular event rates from 3 large placebo-controlled trials. It was preliminary information from one of these long-term trials, the APPROVe trial, that led to Merck's decision to voluntarily withdraw Vioxx.

When Merck made the decision to voluntarily withdraw Vioxx from the market, we stated that we believed that it would have been possible to continue to market Vioxx with labeling that would incorporate the data from the APPROVe trial. We concluded, however, based on the science available at that time, that a voluntary withdrawal of the medicine was the responsible course to take given the availability of alternative therapies and the questions raised by the data.

Since that time new cardiovascular safety data for other COX-2 inhibitors have become available and were reported on just this week in the New England Journal of Medicine.

We look forward to hearing and seeing presentations of these data and to hearing discussions and interpretation of them during this advisory committee meeting.

Thank you, and now I would like to turn the podium over to Dr. Ned Braunstein.