

Sponsor Presentation (Pfizer): Celebrex (Celecoxib): Introduction: Joseph Feczko MD

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

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Highlights

- **APC TRIAL:** Recent preliminary findings from the APC trial should be evaluated in the context of the “large body of prior data on Celebrex.”
- **EXTENSIVE DATABASE AND ANALYSIS:** Pfizer has been extensively studied in clinical trials and epidemiologic studies, and a large meta-analysis of Pfizer’s randomized trials database has been performed.
- **COMPARISONS BETWEEN DRUGS:** The Pfizer presentation will discuss similarities and differences between COX-2 compounds, and also similarities and differences between celecoxib and non-selective NSAIDs.

Presentation Text

Dr. Wood, thank you. I will keep these introductory remarks brief, briefer than I was planning. I will just introduce our presentation today. I am Dr. Joseph Feczko. I am President of Worldwide Development at Pfizer.

I would like to thank the Food and Drug Administration and the advisory committee for this opportunity for Pfizer to share their data that demonstrates the cardiovascular safety profiles of our COX-2 inhibitors, Celebrex and Bextra,

especially in comparison to the non-selective NSAIDs.

For Celebrex questions arose recently from the preliminary data from a longer-term study, the APC trial sponsored by the National Cancer Institute. A cancer prevention trial would suggest an increase in cardiovascular risk compared to placebo for patients taking Celebrex at daily doses of 400 mg and 800 mg per day. The important findings must, and will, be put in context and evaluated

with the large body of prior data on Celebrex.

Celebrex has been extensively studied both by Pfizer and by independent investigators in randomized, controlled clinical trials and epidemiologic studies. With all this research, we continue to investigate GI toleration in arthritis patients and the ability to treat rare form of precancerous polyps, familial adenomatous polyps, for which we have an indication. We also are continuing to study Celebrex in cancer prevention, and we have a large number of trials in cancer treatment where Celebrex is added to conventional chemotherapy for a variety of cancers.

In a moment Dr. Kenneth Verburg will outline for you several bodies of data.

- One, he will review the cumulative safety tolerability data for Celebrex.
- Two, he will review the results of a new meta-analysis of Pfizer's database, one of the largest analyses of its kind conducted to date. This includes extensive information looking at Celebrex in comparison to other widely prescribed non-selective NSAIDs.
- Third, Dr. Verburg will also present results of multiple published epidemiological studies which show a consistent lack of the cardiovascular signal for Celebrex when used in the real-world setting in arthritis patients.

Throughout the presentation we will also look at this issue of whether or not there are differences or similarities in a class of COX-2 compounds or across the non-

selective NSAIDs. I think we all know that within a class of compounds there are still opportunities for individual variation of individual drugs. We see that frequently, especially when we look at severity, incidence or frequency of uncommon or common side effects. So, we hope to bring this out within our presentation.

With no further ado, I will turn this over to Dr. Kenneth Verburg and we will be happy to delve into any other questions that you have at the end of his presentation.