



Pfizer Statement on Today's Joint Meeting of FDA Advisory Committees

Tuesday, February 11, 2014 - 09:04am

Pfizer agrees with the recommendation of the joint meeting of the FDA Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee that the available data do not support a conclusion that naproxen has a lower risk of cardiovascular thrombotic events as compared to other non-steroidal anti-inflammatory drugs (NSAIDs).

Based on Pfizer's review of the data discussed, we believe there is insufficient evidence to make this type of distinction. Differentiation between NSAIDs on cardiovascular safety should be based on substantial scientific evidence.

Pfizer is sponsoring a study that may provide substantial evidence. PRECISION is a large, ongoing, well-controlled, randomized clinical trial designed in agreement with FDA to assess the relative long-term cardiovascular safety of CELEBREX compared to prescription doses of two commonly prescribed NSAIDs, ibuprofen and naproxen, in the treatment of arthritis pain. It is an important study that will provide meaningful information on the cardiovascular safety of these medicines.

Although advisory committees provide recommendations to the FDA, FDA makes final regulatory decisions.

Patient safety and appropriate use of our medicines are top priorities at Pfizer. For more than 30 years, Pfizer NSAID medicines have helped people relieve their headaches, arthritis symptoms and other causes of pain or inflammation. We are committed to ongoing safety monitoring of our medicines.

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