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AN UPDATE ON BEXTRA AND CELEBREX

WINNIPEG, April 8th, 2005 – Only 190 days after the withdrawal of Vioxx® (rofecoxib), another COX-2 inhibitor, Bextra™ (valdecoxib) is edging closer to the same fate. Unlike the rofecoxib situation where Merck voluntarily withdrew Vioxx® from the market worldwide, in this case, Health Canada has asked Pfizer to voluntarily discontinue sales of Bextra™. Pfizer has agreed to discontinue sales of the product; however, in a press release made yesterday, stated that they “disagree with the decision by Health Canada” and that they will “explore options with Health Canada under which the company might be permitted to resume making Bextra™ available to Canadian physicians and patients.” However, Pfizer does recommend patients to stop taking Bextra™, and contact their physicians for alternative treatment options.

The advisory from Health Canada states that its “decision is based on an ongoing review of information with regard to serious, life-threatening skin reactions.” The specific concerns of these skin reactions were discussed in Health Canada Advisory published in December 2004. At that time, the Bextra™ product monograph was revised.

Health Canada is also recommending important new usage restrictions for Celebrex™ (celecoxib), another COX-2 inhibitor.

Cardiovascular Risk

In March of 2005 a key article on Bextra™’s cardiac safety risk was published. The article discusses information on the drug’s value in reducing postoperative pain following cardiovascular surgery. As a result of this research, the Bextra™ product monograph was revised to indicate that the drug has not been approved for use in any post-operative setting.

While Bextra™ has been removed from the market, Celebrex™ is the only COX-2 drug still available. However, because of evidence of cardiovascular risk, Health Canada has required the following new restrictions on Celebrex™ use:

- Patients who have had a heart attack or stroke, experienced serious chest pain related to heart disease, or who have had serious diseases of the heart (such as congestive heart failure) should not use Celebrex™
- Patients who have significant risk factors for heart attack or stroke should be made aware that using Celebrex™ may increase this risk
- Celebrex™ should be prescribed and used at the lowest possible dose, and for the shortest, necessary period of time



What to Tell Patients

On the grounds of the Health Canada warning and the recommendations from Pfizer, it is appropriate for patients to discontinue Bextra™ therapy. In light of Health Canada's primary concerns of over serious skin reactions (that more commonly occur in the first two weeks of therapy) in addition to the known potential cardiac risks of the drug, filling initial prescriptions for Bextra™ is inadvisable. For patients currently taking Bextra™, and who wish to continue it until they are able to consult their physicians, they should be advised of the risks associated with therapy, and the strong recommendations made by Health Canada and Pfizer.

