European Medicines Agency
Press office

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Press release

EMEA statement on celecoxib

The European Medicines Agency (EMEA) has been informed by Pfizer of a clinical study that shows an increased risk of major fatal or non-fatal cardiovascular events (i.e. acute myocardial infarction and stroke) in patients taking celecoxib compared to patients given placebo. Celecoxib is a member of the class of medicines called COX-2 inhibitors.

This study, conducted by the US National Cancer Institute, the Adenoma Prevention with Celecoxib trial (ACP), involved 2,400 patients with an average duration of 33 months' treatment, taking 400 mg or 800 mg celecoxib per day. The increased risk appears to depend on dosage, with a 2.5 fold increase with the lower dose of experiencing a major cardiovascular event compared to those taking placebo, and a 3.4 fold increase with the higher dose. The NCI data safety and monitoring board, which is independent of Pfizer, has decided to stop this trial immediately.

A separate trial sponsored by Pfizer (Prevention of Spontaneous Adenoma Polyps (PreSAP) trial), does not appear to confirm this risk. This trial has also now been stopped based on the results of the ACP trial.

The EMEA has requested the results of both studies and will review them as soon as they are available.

In parallel, the European Medicines Agency is currently conducting a review of all COX-2 inhibitor medicines, looking at cardiovascular safety.

Information to prescribers and patients issued by the EMEA on 22 October 2004 remains valid:

- Prescribers are advised to follow carefully the latest version of the summary of product characteristics for COX-2 inhibitors, especially regarding the warnings and precautions in patients with a history of cardiovascular disease.

- Patients should be aware that all COX-2 medicines available in Europe already contain warnings regarding heart problems. If you have any concerns about your treatment you are advised to consult your prescriber.

--ENDS--

NOTES FOR EDITORS

1. The 22 October 2004 EMEA statement following the withdrawal of Vioxx (rofecoxib) is available [here].

2. COX-2 inhibitors (cyclo-oxygenase-2 inhibitors) are non-steroidal anti-inflammatory medicines (NSAID). They are approved in the European Union for use in a number of indications – see notes 3 and 4 for information on the different products.

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3. Information on the outcome of the EMEA review of nationally approved COX-2 medicinal products (containing celecoxib, etoricoxib and rofecoxib) was published in June 2004 and can be found [here].

4. More information on centrally authorised COX-2 inhibitors can be found in the European public assessment reports [here] for Bextra/Valdyn (valdecoxib), [here] for Dynastat/Rayzon (parecoxib) and [here] for Onsenal (celecoxib).

5. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int

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