European Medicines Agency
Press office

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Update from the European Medicines Agency on COX-2 inhibitors

As part of the ongoing review of **COX-2 inhibitors**, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) held hearings with Pfizer (for celecoxib, parecoxib and valdecoxib), Merck Sharp & Dohme (for etoricoxib) and Novartis (for lumiracoxib) on 18 January 2005.

Further to its assessment of data submitted on celecoxib, the Committee requested further clarifications and analyses, in particular of data from the Adenoma Prevention with Celecoxib (APC) and Prevention of Spontaneous Adenoma Polyps (PreSAP) studies.

The review includes Onsenal (celecoxib), which is used in the orphan (rare) indication in the treatment of adenomatous intestinal polyps in familial adenomatous polyposis. This is a similar treatment area as looked at in the APC and PreSAP celecoxib studies and also the APPROVe study that led to the withdrawal of Vioxx (rofecoxib). Following discussions with the Committee, Pfizer has agreed not to launch Onsenal in the European Union pending finalisation of the assessment.

Data on other COX-2 inhibitors (etoricoxib, lumiracoxib, parecoxib and valdecoxib) are currently being assessed. The CHMP will continue its discussions on the review at its next meeting on 14-17 February 2005.

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NOTES:

1. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at http://www.emea.eu.int
2. The EMEA review of the COX-2 inhibitor class of medicines was announced on 22 October 2004 and can be found [here]. The EMEA issued further statements on 17 December 2004 [here] and 22 December 2004 [here]. A question and answer document was published on 23 December 2004 [here].

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