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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 10-13 December 2007

Initial evaluation of medicines

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted three positive opinions, two of which related to generic medicines, recommending the granting of a marketing authorisation for the following medicines:

- **Tyverb** (lapatinib), from GlaxoSmithKline, indicated, in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have previously been treated. The CHMP recommended a 'conditional approval' for Tyverb, since there is more information to come about the medicine, in particular about its efficacy. EMEA review began on 25 October 2006 with an active review time of 202 days.
- **Myfenax** and **Mycophenolate mofetil Teva** (mycophenolate mofetil), from TEVA Pharma B.V, indicated for the prevention of acute transplant rejection in patients receiving allogeneic kidney, heart or liver transplants. The two medicines are generics of CellCept, which has been authorised in the EU since February 1996. EMEA review began on 20 July 2007 with an active review time of 138 days.

The CHMP also adopted two negative opinions recommending the refusal of a marketing authorisation, for the following medicines:

- **Kiacta** (eprodisate disodium), from Neurochem Luco II SARL, intended to be used in the treatment of amyloid A (AA) amyloidosis. Kiacta was designated as orphan medicinal product. EMEA review began on 27 September 2006 with an active review time of 202 days.
- **Rhucin** (rhC1INH), from Pharming Group N.V., intended for the treatment of acute attacks of angioedema in patients with hereditary angioedema. Rhucin was designated as orphan medicinal product. EMEA review began on 16 August 2006 with an active review time of 176 days.

Separate question-and-answer documents explaining the grounds for the negative opinions for Kiacta and Rhucin are available on the EMEA website.

Extensions of indication

The CHMP gave positive opinions for applications for extension of indication, adding new treatment options for the following previously approved medicines:

- **Avastin** (bevacizumab), from Roche Registration Ltd, to extend the indication in the treatment of metastatic colorectal cancer in combination with fluropyrimidine-based chemotherapy. Avastin is currently authorised for first-line treatment of patients with certain types of cancer of the colon or rectum, breast cancer, and non-small cell lung cancer. During the November meeting of the CHMP, a recommendation was adopted to also include combination therapy of kidney cancer.
- **Humira** (adalimumab), from Abbott Laboratories, to include reduction in the rate of progression of joint damage and improvement of physical function in the psoriatic arthritis indication. Humira is currently indicated in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease.
- **Mabthera** (rituximab), from Roche Registration Ltd, to extend the indication to include first-line treatment of follicular non-Hodgkin's lymphoma in combination with chemotherapy. Mabthera is

currently authorised for first- and second-line treatment of follicular lymphoma and for treatment of CD20 positive diffuse large B cell non- Hodgkin's lymphoma.

- **Xeloda** (capecitabine), from Roche Registration Ltd, to extend the indication in the treatment of patients with metastatic colorectal cancer. Xeloda is currently approved for the treatment of patients with stage III (Dukes' stage C) colon cancer, as first line monotherapy in metastatic colorectal cancer, advanced gastric cancer, locally advanced or metastatic breast cancer.

Summaries of opinions for all mentioned products, including their full indication, can be found here.

Review procedures under Article 107
The CHMP has recommended the withdrawal of the marketing authorisations for all lumiracoxib-containing medicines, because of the risk of serious side effects affecting the liver. Lumiracoxib is a non-steroidal anti-inflammatory drug (NSAID) that belongs to the group 'COX-2 inhibitors'. It is used for symptomatic relief in the treatment of osteoarthritis of the hip and knee.

A separate press release and a question-and-answer document with more detailed information are available on the EMEA website.

Referral procedures concluded
The CHMP concluded two referral procedures. Referrals are initiated where there is a disagreement between Member States concerning the marketing authorisation of medicines authorised at national level.

The CHMP recommended the refusal of an extension of indication for **Belara** and **Belanca** (30 micrograms ethinyl estradiol plus 2 mg chlormadinone acetate) from Grünenthal, because the data submitted was considered insufficient to demonstrate efficacy in the applied indication (treatment of women suffering from acne). Belara and Balanca are currently authorised in a number of Member States as oral contraceptives. The referral procedure was carried out under Article 6 (12) of Commission Regulation (EC) No 1084/2003

The CHMP recommended approval of the proposed packaging concept for **Belanette 0.020 mg, 3mg film coated tablet** and **Yasminelle 0.020 mg, 3mg film coated tablet**, from Bayer Schering Pharma AG. Belanette and Yasminelle are authorised in a number of Member States as oral contraceptives. The procedure was initiated under Article 5 (11) of Commission Regulation (EC) No 1084/2003.

Referral procedures started
The CHMP started referral procedures for five medicines containing atorvastatin calcium, namely **Atorvatyrol**, (10, 20, 40, 80 mg) from Sandoz GmbH Austria , **Atorvac** (10, 20, 40, 80 mg) and **Atorvastatin Hexal**,(30, 60 mg) both from Hexal Pharma GmbH Austria, **Atorvis** (10, 20, 40, 80 mg)**,** from Sandoz GmbH Austria and **Atorvapharm** (10, 20, 40, 80 mg**),** from 1A Pharma GmbH Austria because of concerns that bioequivalence with the reference medicine has not been demonstrated sufficiently. The medicines are intended for the treatment of hypercholesterolaemia and prevention of cardiovascular disease. The referral procedure has been initiated under Article 29 of Directive 2001/83/EC as amended.

A more detailed CHMP meeting report will be published shortly.

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