European Medicines Agency
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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 22-25 June 2009

First positive opinion for advanced therapy medicinal product adopted
The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted its first positive opinion for an advanced therapy medicinal product, recommending that **ChondroCelect**, from TiGenix NV, be granted a marketing authorisation. The CHMP adopted its opinion on the basis of a draft opinion prepared by the Agency's new Committee for Advanced Therapies (CAT).

ChondroCelect is a cell-based medicine consisting of chondrocytes (cartilage-forming cells) expanded *in vitro*. The chondrocytes are taken from a small biopsy of healthy cartilage from the patient, grown outside the body, and then re-implanted during surgery. ChondroCelect is used to repair single symptomatic cartilage defects of the femoral condyle (the end of the thighbone) in the knee.

More information is available in a separate press release.

Other positive opinions for new medicines
The CHMP adopted positive opinions, recommending the granting of a marketing authorisation, for the following medicines:

- **Cimzia** (certolizumab pegol), from UCB Pharma SA, intended for the treatment of rheumatoid arthritis. The review began on 25 June 2008, with an active review time of 205 days.
- **Javlor** (vinflunine ditartrate), from Pierre Fabre Medicament, intended for the treatment of carcinoma of urothelial tract. The review began on 27 February 2008, with an active review time of 196 days.
- **Onglyza** (saxagliptin), from Bristol-Myers Squibb/AstraZeneca EEIG, intended for the treatment of type 2 diabetes mellitus. The review began on 23 July 2008, with an active review time of 205 days.
- **Simponi** (golimumab), from Centocor BV, intended for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. The review began on 26 March 2008, with an active review time of 177 days.

Positive opinions for generic medicines
The Committee adopted positive opinions for the following generic medicines, for which a reference medicine is already authorised in the European Union:

- **Vizarsin** (sildenafil), from Krka, d.d., Novo mesto, a generic of Viagra, intended to treat erectile dysfunction.
- **Topotecan Teva** (topotecan hydrochloride), from Teva Pharma B.V., a generic of Hycamtin, intended for the treatment of ovary carcinoma, small cell lung cancer and carcinoma of the cervix.
- **Clopidogrel Acino Pharma** (clopidogrel, as besilate), **Clopidogrel Acino Pharma GmbH** (clopidogrel, as besilate), **Clopidogrel ratiopharm** (clopidogrel, as besilate), **Clopidogrel Sandoz** (clopidogrel, as besilate), all from Acino Pharma GmbH.
- **Clopidogrel Krka** (clopidogrel, as hydrochloride), from Krka, d.d., Novo mesto, **Clopidogrel DURA** (clopidogrel, as hydrochloride), from Mylan dura GmbH, **Clopidogrel HCS** (clopidogrel,

* The orphan drug reference to Cayston has been inserted on page 2.

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as hydrochloride), from HCS bvba, **Clopidogrel Mylan** (clopidogrel, as hydrochloride), from Mylan S.A.S., **Clopidogrel Qualimed** (clopidogrel, as hydrochloride), from Qualimed, **Clopidogrel TAD** (clopidogrel, as hydrochloride), from Tad Pharma GmbH, **Zopya** (clopidogrel, as hydrochloride), from Norpharm Regulatory Services Ltd.

- **Zyllt (**clopidogrel, as hydrogen sulphate) and **Zylagren** (clopidogrel, as hydrogen sulphate), both from Krka, d.d., Novo mesto.

All mentioned clopidogrel-containing medicines are generics of Plavix and are intended for the prevention of atherothrombotic events.

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

Re-examination procedure concluded

The CHMP adopted a final positive opinion recommending the granting of a marketing authorisation for **Cayston** (aztreonam lysine), from Gilead Sciences International Ltd, following a re-examination of its previous negative opinion, adopted in March 2009. Cayston is intended for the suppressive therapy of chronic pulmonary infection caused by *Pseudomonas aeruginosa* bacteria in adults with cystic fibrosis. Cayston is the **57th orphan medicine** to receive a positive opinion from the CHMP.

More information on the re-examination procedure is available in a separate question-and-answer document.

Extension of indication – positive opinions

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

- **Avastin** (bevacizumab), from Roche Registration Ltd., to extend the indication to add combination therapy with docetaxel chemotherapy to the first-line treatment of metastatic breast cancer. Avastin is already authorised in this indication in combination with paclixatel. It is also authorised for first-line combination therapy of patients with certain types of cancer of the colon or rectum, the kidney and non-small cell lung cancer.
- **Januvia** (sitagliptin), **Tesavel** (sitagliptin) and **Xelevia** (sitagliptin), all from Merck Sharp & Dohme, to extend the indication to allow the use of sitagliptin as monotherapy in patients for whom metformin is inappropriate due to contraindications or intolerance. Januvia, Tesavel and Xelevia are currently only authorised as combination therapy.
- **Xolair** (omalizumab), from Novartis Europharm Ltd., to extend the existing indication to paediatric patients from 6 to less than 12 years of age. Xolair currently is used as add-on therapy to improve the control of severe persistent allergic asthma in adult and adolescent patients 12 years of age and over.

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

European Medicines Agency recommends withdrawal of marketing authorisations for dextropropoxyphene-containing medicines

Finalising a review under Article 31 of Directive 2001/83/EC, as amended, the CHMP concluded that the risks of dextropropoxyphene-containing medicines, particularly the risk of potentially fatal overdose, are greater than their benefits. The CHMP therefore recommended that the marketing authorisations for these medicines be withdrawn across the European Union. The withdrawal will be gradual to allow time for the safe transfer of patients to appropriate alternative therapies, in line with national recommendations.

Dextropropoxyphene-containing medicines are painkillers used to treat acute and chronic pain. They have been available as prescription-only medicines for about 40 years, containing either

dextropropoxyphene on its own or in combination, primarily with paracetamol, as tablets, capsules, suppositories and solutions for injection.

More information is available in a separate press release and question-and-answer document.

Other referral procedures concluded

The CHMP concluded a number of referral procedures under Article 29 of Directive 2001/83/EC, as amended. This type of procedure is initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure. The medicines concerned are:

- **Fentrix** and associated names (fentanyl), 25, 50, 75 and 100 µg/h transdermal patches, from Helm Pharmaceuticals GmbH, indicated for severe chronic pain. The procedure was initiated because of disagreements regarding the safety of the medicine. The CHMP concluded that the transdermal patch did not pose a risk to public health and recommended the granting of a marketing authorisation.
- **Teicoplanin Hospira** and associated names (teicoplanin), 200 mg and 400 mg powder and solvent for injection or infusion, from Hospira UK Limited, indicated for the treatment of specific bacterial infections. The procedure was initiated because of concerns that the bioequivalence to the reference medicine has not been adequately demonstrated. The CHMP concluded that Teicoplanin Hospira is not a generic to the reference medicine and recommended the refusal of a marketing authorisation.
- **Avalox** and associated names (moxifloxacin hydrocloride), 400 mg solution for infusion, and **Octegra** and associated names (moxifloxacin hydrocloride), 400 mg solution for infusion, both from Bayer Vital GmbH, indicated for the second-line treatment of community acquired pneumonia and complicated skin and skin structure infections. Both procedures were initiated because of potentially serious public health concerns related to the use of these medicines. The CHMP concluded that these medicines are approvable but that their benefit-risk balance is only positive when used as a second-line indication. The Committee recommended the granting of a marketing authorisation.

The CHMP concluded a number of referral procedures under Article 30 of Directive 2001/83/EC, as amended. This type of procedure is initiated with a view to harmonising the product information for medicines authorised at the level of the Member States. The CHMP recommended the amendment of the Summary of Product Characteristics, labelling and package leaflet for the following medicinal products:

- **Augmentin** and associated names, (amoxicillin and clavulanic acid), from GSK group of companies and associated companies, used as an anti-infective. The CHMP adopted a harmonised Product Information.
- **Topamax** and associated names, (topiramate), from Johnson & Johnson group of companies and associated companies, used as an anti-convulsant. The CHMP adopted a harmonised Product Information.

Question-and-answer documents with more information about these referrals can be found here.

A more detailed CHMP meeting report will be published shortly.

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