European Medicines Agency
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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 17-20 November 2008

Initial evaluation
The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions, recommending the granting of a marketing authorisation, for the following new medicines.

- **Nplate** (romiplostim), from Amgen Europe B.V., for the treatment of adult chronic immune idiopathic thrombocytopenic purpura (ITP). Nplate is **the 51st orphan medicine** to receive a positive opinion by the CHMP. EMEA review began on 21 November 2007 with an active review time of 203 days.
- **Rasilez HCT (**aliskiren hemifumarate/hydrochlorothiazide), from Novartis Europharm Ltd., for the treatment of essential hypertension in adults. Rasilez HCT is indicated in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone. Rasilez HCT is indicated as substitution therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination**.** EMEA review began on 26 December 2007 with an active review time of 195 days.
- **RoActemra** (tocilizumab), from Roche Registration Limited, for the treatment in combination with methotrexate of moderate to severe active rheumatoid arthritis in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease modifying anti-rheumatic drugs or tumour necrosis factor antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate. EMEA review began on 26 December 2007 with an active review time of 205 days.
- **Stelara** (ustekinumab), from Janssen-Cilag International NV, for the treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to other systemic therapies. EMEA review began on 26 December 2007 with an active review time of 204 days.
- **Valdoxan/Thymanax** (agomelatine), from Les Laboratories Servier, for the treatment of major depressive episodes in adults. EMEA review began on 27 September 2007 with an active review time of 203 days.
- **Zevtera** (ceftobiprole medocaril), from Jannsen-Cilag International NV, for the treatment of complicated skin and soft tissue infections. EMEA review began on 20 July 2007 with an active review time of 175 days.

Biosimilar medicines
The Committee adopted a positive opinion for **Filgrastim Hexal (**filgrastim) from Hexal Biotech Forschungs GmbH and **Zarzio (**filgrastim), from Sandoz GmbH, for the treatment of neutropenia. Both medicines have been shown to be similar to Neupogen, from Amgen GmbH, the reference medicinal product already authorised in the European Union (EU), in the indication applied for. EMEA review began on 27 September 2007 with an active review time of 204 days.

Negative opinion
The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Ixempra** (ixapebilone), from Bristol-Myers Squibb EEIG. Ixempra was intended to be used for the

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treatment of metastatic or locally advanced breast cancer. EMEA review began on 25 October 2007 with an active review time of 203 days.

A separate question-and-answer document with more detailed information about the negative opinion is available here.

Re-examination procedures concluded
Following the re-examination of the negative opinion adopted on 24 July 2008, the CHMP confirmed its previous position and adopted a final negative opinion for **Sovrima** (idebenone), from Santhera AG. Sovrima was intended to be used for the treatment of Friedreich's Ataxia, an inherited disease that causes progressive damage to the nervous system. It was designated as an orphan medicine.

A separate question-and-answer document with more information about the re-examination procedure is available here[*].

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

- **Enbrel** (etanercept), from Wyeth Europe Ltd, to extend the indication to include the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by or are intolerant to other systemic therapies or phototherapies. Enbrel is currently indicated for the treatment of rheumatoid arthritis, polyarticular juvenile idiophatic arthritis, psoriatic arthritis, ankylosing spondylitis, and moderate to severe plaque psoriasis in adults.
- **Prezista** (darunavir), from Janssen-Cilag International NV, to extend the indication to include the treatment of antiretroviral-therapy naïve HIV-1 infected adults. This indication comes with a new strength of 400 mg film-coated tablet. Prezista is currently indicated as a combination treatment of HIV-1 infection in highly pre treated adult patients who failed more than one regimen containing a protease inhibitor.

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

Recommendation to suspend the marketing authorisation of Ionsys
The European Medicines Agency (EMEA) has recommended the suspension of the marketing authorisation of Ionsys (fentanyl hydrochloride), from Janssen-Cilag International NV, because of a defect with the delivery system of the medicine that could lead to patients being overdosed.

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

Referral procedures concluded
The CHMP concluded a referral procedure under Article 29 of Directive 2001/83/EC, as amended, for **Implanon** (etonogrestel) 68mg subdermal implant, from N.V. Organon/Organon B.V., indicated for contraception. The CHMP was of the opinion that Implanon is an effective method of contraception with no apparent safety concerns and that the benefits of the medicine outweigh the risks of Implanon and that a marketing authorisation should be granted.

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 CHMP concluded a referral procedure under Article 30 of Directive 2001/83/EC, as amended, for **Diovan and associated names** (valsartan[**])**,** from Novartis group of companies and associated

[*] corr. Link has been changed to link to the correct document
[**] corr. 2 The active substance has been changed from valsartan/hydrochlorothiazide to valsartan only

companies, intended for the treatment of essential hypertension, recent myocardial infarction and heart failure. The CHMP recommended the harmonisation of the product information.

This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level.

Referral procedures started

The CHMP started a referral procedure under Article 31 of Directive 2001/83/EC, as amended, for **Gadolinium-containing contrast agents** (gadodiamide, gadopentetic acid, gadobenic acid, gadoxetic acid, gadoteridol, gadobutrol and gadoteric acid), intended for use in patients who are undergoing magnetic resonance imaging, a special type of scan where images of the internal organs are taken. The procedure was initiated by Denmark due to the lack of harmonisation of the product information and risk minimisation measures in relation to the use of these medicines in special groups of patients.

Referrals under Article 31 of Directive 2001/83/EC, as amended, are initiated in cases involving the interests of the Community or concerns relating to the protection of public health.

In parallel, the European Commission initiated a procedure under Article 20 of Regulation (EC) No 726/2004 for the two centrally authorised gadolinium-containing contrast agents, Optimark (gadoversetamide) and Vasovist (gadofosveset) on the same grounds. These types of procedures are initiated in cases where there are public health concerns with a centrally authorised medicine.

The CHMP started a number of referral procedures under Article 29 of Directive 2001/83/EC, as amended. This type of procedures 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 medicinal products concerned are:

- **Uman Big 180 IU/ml solution for injection** (Human Hepatitis B Immunoglobulin), from Kedrion SpA, indicated for immunoprophylaxis of hepatitis B in specific circumstances.
- **Betavert N 8/16 mg** (betahistine dihydrochloride), from Henning Arzniemittel GmbH&Co. KG, used as an anti-vertigo drug.
- **Bleomycine 15 U PCH** (bleomycin sulphate), from Pharmachemie/NL, used as an anti-cancer agent.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended, for **Valtrex** and associated names (valaciclovir), from GSK group of companies and associated companies, used in the treatment of herpes simplex and herpes zoster (shingles).

A more detailed CHMP meeting report will be published shortly.

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