News from the EMA

Activities of the CHMP

During its meeting from 21-24 May 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted:

seven positive opinions for the **granting of a marketing authorisation** for:

- **Bretaris Genuair and Eklira Genuair** (aclidinium bromide) inhalation powder, from Almirall S.A., for the maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD).

- **Fycompa** (perampanel) film-coated tablet, from Eisai, film-coated tablet intended for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.

- **Inlyta** (axatinib) film-coated tablets, from Pfizer, an orphan medicinal product intended for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.

- **Jentadueto** (linagliptin / metformin hydrochloride) film-coated tablets, from Boehringer Ingelheim, intended for the treatment of type 2 diabetes mellitus in adults.

- **Kalydeco** (ivacaftor) film-coated tablet, an orphan medicinal product from Vertex, intended for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene.

- **Novothirteen** (Catridecacog) powder for solution for injection, an orphan medicinal product from Novo Nordisk, intended for long term prophylactic treatment of bleeding in patients 6 years and above with congenital factor XIII A-subunit deficiency.

- a positive opinion for the **approval** of the following **generic product:**

- **Zoledronic acid medac** concentrate for solution for infusion and solution for infusion, from medac Gesellschaft für klinische Spezialpräparate, intended for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone, and the treatment of adult patients with tumour-induced hypercalcaemia (TIH).

- four positive opinions for the following extensions of indications:

- **Osseor and Protelos** (strontium ranelate), from Servier, are also indicated for treatment of osteoporosis in men at increased risk of fracture.

- **Votrient** (pazopanib), from Glaxo, is also indicated for treatment of soft tissue sarcoma (STS).

- **Zonegram** (zonisamide), from Eisai, is also indicated for the monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy.

Pharmacovigilance

Finalisation of reviews: For the following medicine a quality review was finalised: **MabThera** (rituximab)**:** The CHMP has concluded that the batches of the active substance of this medicine produced at the Vacaville manufacturing site in the United States do not present a risk to public health. MabThera, from Roche, is indicated in non-Hodgkin's lymphoma, chronic lymphocytic leukaemia (CLL) and rheumatoid arthritis.

For the following medicine a safety review was finalised:
Pradaxa (dabigatran etexilate): The CHMP concluded that the benefits of this blood thinner, from Boehringer Ingelheim, continue to outweigh its risks and recommended updating of the product information to give clearer guidance to doctors and patients on how to reduce and manage the risk of bleeding.
Outcome of harmonisation referrals:
For the following products the CHMP recommended a harmonised prescribing information:
Flolan (epoprostenol) solution for infusion, from GSK, used to prevent blood clotting during haemodialysis
Tavanic (levofloxacin) tablets or solution for infusion, from Sanofi-Aventis, used to treat various infections
Zinat (cefuroxim axetile) tablets and granules for an oral suspension and **Zinacef** powder for solution/suspension for infusion or injection, from GSK, used to treat certain bacterial infections.
Start of reviews for the following medicines:
Evicel (human fibrinogen/human thrombin) (triggered by the European Commission) and **fibrinogen-containing sealants** administered as spray (triggered by UK) to review the benefit-risk balance following reports of air embolism after administration of the product as spray.
Methysergide-containing products (triggered by France) to review the safety in certain indications due to safety concerns regarding fibrotic risks
Start of an arbitration procedure for:
Furosemide Vitabalans (triggered by Estonia) due to disagreements regarding the benefit-risk ratio of this product.

Date of the next CHMP meeting: 18 – 21 June 2012.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu