EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Paediatric Committee (PDCO)

PDCO monthly report of opinions on paediatric investigation plans and other activities

16-18 July 2014

Opinions on paediatric investigation plans

The Paediatric Committee (PDCO) adopted opinions agreeing paediatric investigation plans (PIPs) for the following medicines:

- Apremilast, from Celgene Europe Limited, for the treatment of Behcet disease;
- 4-{[(1R,2s,3S,5s,7s)-5-Hydroxy-2-adamantyl]amino}-1H-pyrrolo[2,3-b]pyridine-5-carboxamide monohydrobromide, from Janssen Cilag International NV, for the treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis);
- Ertugliflozin, from Merck Sharp and Dohme (Europe), Inc., for the treatment of type II diabetes mellitus;
- Propan-2-yl N-[(S)-({[(2R)-1-(6-amino-9H-purin-9-yl)propan-2-yl]-oxy}methyl)(phenoxy) phosphoryl]-l-alaninate, (2E)-but-2-enedioate (2:1) (GS-7340), from Gilead Sciences International Ltd., for the treatment of chronic viral hepatitis B;
- Trifarotene (CD5789), from Galderma International, for the treatment of acne.

A PIP sets out a programme for the development of a medicine in the paediatric population. The PIP aims to generate the necessary quality, safety and efficacy data through studies to support the authorisation of the medicine for use in children of all ages. These data have to be submitted to the European Medicines Agency, or national competent authorities, as part of an application for a marketing authorisation for a new medicine, or for one covered by a patent. In some cases, a PIP may include a waiver of the studies in one or more paediatric subsets, or a deferral.

Opinions on product-specific waivers

The PDCO adopted positive opinions for product-specific waivers, recommending that the obligation to submit data obtained through clinical studies with children be waived in all subsets of the paediatric population, for the following medicines:

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- Bromfenac (sodium sesquihydrate), from InSite Vision Incorporated, for the treatment of postoperative pain and inflammation associated with cataract surgery and prevention of postoperative pain and inflammation associated with cataract surgery;
- Perindopril / bisoprolol, from Les Laboratoires Servier, for the treatment of ischaemic coronary artery disorders, treatment of hypertension and treatment of heart failure;
- Rosuvastatin / valsartan, from Krka, d.d., Novo mesto, for the treatment of dyslipidaemia, treatment of hypertension and prevention of cardiovascular events;
- Antisense oligonucleotide (30-mer) with nucleotide sequence 5′ - GTAATTGCGGCAAGAAGAATTGTTTCTGTC-3′ (CODA001), from CoDa Therapeutics Inc, for the treatment of venous leg ulcer.

The PDCO adopted 1 opinion on the **refusal** of a request for waiver for:

- (R)-2-[3-({Benzoxazol-2-yl[3-(4-methoxyphenoxy)propyl]amino}methyl)phenoxy]butanoic acid, from Kowa Research Europe Ltd, for the reduction of residual cardiovascular events in patients with diabetes.

Waivers can be issued if there is evidence that the medicine concerned is likely to be ineffective or unsafe in the paediatric population, or that the disease or condition targeted occurs only in adult populations, or that the medicine, or the performance of trials, does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Opinions on modifications to an agreed PIP

The PDCO also adopts, every month, opinions on modifications to an agreed PIP, which can be requested by the applicant when the plan is no longer appropriate or when there are difficulties that render the plan unworkable. The PDCO adopted positive opinions, agreeing change(s), for the following products:

- Tapentadol (hydrochloride), from Grünenthal GmbH, for the treatment of acute pain;
- Golimumab, from Janssen Biologics BV, for the treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, and juvenile idiopathic arthritis);
- Insulin degludec / insulin aspart, from Novo Nordisk A/S, for the treatment of type I diabetes mellitus and treatment of type II diabetes mellitus;
- N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid, from GlaxoSmithKline Biologicals s.a., for the prevention of Meningococcal Disease;
- Idelalisib, from Gilead Sciences International Ltd, for the treatment of mature B-cell neoplasm;
- Ferric citrate (coordination complex), from Keryx Biopharmaceuticals, Inc., for the treatment of hyperphosphataemia;
- Tofacitinib, from Pfizer Limited, for the treatment of psoriasis;
- Dalbavancin, from Durata Therapeutics International B.V., for the treatment of skin and soft tissue infections;

- Maraviroc, from ViiV Healthcare UK Limited, for the treatment of Human immunodeficiency virus infection;
- Cobicistat, from Gilead Sciences International Limited, for the treatment of human immunodeficiency virus type-1 (HIV-1) infection;
- Enalapril (maleate), from Proveca Limited, for the treatment of heart failure;
- Tadalafil, from Eli Lilly and Company Ltd, for the treatment of pulmonary arterial hypertension.

The PDCO adopted 2 opinions on the **refusal** of modifications to an agreed PIP for:

- Influenza virus surface antigens (H5N1 or H1N1 strains), from Novartis Vaccines and Diagnostics S.r.l., for the prevention of influenza;
- Telaprevir, from Janssen Infectious Diseases BVBA, for the treatment of chronic hepatitis C.

Withdrawals

The PDCO noted that 4 applications were withdrawn during the late stages of the evaluation (30 days or less before completion of the procedure).

Other matters

The PDCO welcomed the new alternate from Latvia, Dr Kristine Supe.

The next meeting of the PDCO will be held on 13-15 August 2014.

– END –

Notes:

1. As of 26 January 2009, pharmaceutical companies that submit an application for a marketing authorisation for a medicinal product, or those that submit an application for an extension of indication, a new route of administration, or a new pharmaceutical form of a medicinal product already authorised in the European Union, have to provide either the results of studies in children conducted in accordance with an approved PIP, or an Agency's decision on a waiver or on a deferral.

2. PDCO opinions on PIPs and waivers are transformed into Agency's decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/pip_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d129

3. More information about the PDCO and the Paediatric Regulation is available in the Regulatory section of the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000023.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cd

4. This meeting report, together with other information on the work of the Agency's, can be found on the Agency's website: http://www.ema.europa.eu

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