European Medicines Agency

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PRESS RELEASE

Meeting highlights from the Paediatric Committee, 09-11 December 2009

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

- **Teplizumab**, from Eli Lilly and Company Limited, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Givinostat**, from Italfarmaco SpA, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **(1R,2R,4S)-4-{(2R)-2-[(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S, 23S,26R,27R,34aS)-9,27-dihydroxy-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-1,5,11,28,29-pentaoxo-1,4,5,6,9,10,11,12,13,14,21,22, 23,24,25,26,27,28,29,31,32,33,34,34a-tetracosahydro-3H-23,27-epoxypyrido[2,1-c][1,4]oxazacyclohentriacontin-3-yl]propyl}-2-methoxycyclohexyldimethyl-phosphinate (also known as : MK-8669 or AP23573)**, from Merck Sharp and Dohme (Europe), Inc., in the therapeutic area of oncology;
- **Japanese encephalitis virus (strain SA14-14-2 (inactivated))**, from Intercell AG, in the therapeutic area of vaccines.

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:

- **(D-6-n-propyl-8β-ergolinylmethylthioacetyl)-DLys(D-6-n-propyl-8β-ergolinylmethylthioacetyl)-Cys-Tyr-DTrp-Lys-Abu-Cys-Thr-NH2 (BIM 23A760)**, from Ipsen Pharma, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Linagliptin / metformin**, from Boehringer Ingelheim International GmbH, in the therapeutic area of endocrinology-gynaecology-fertility-metabolism;
- **Larvae of Lucilia sericata**, from ZooBiotic Limited, in the therapeutic area of other (woundcare);
- **Atorvastatin (L-lysine salt) / amlodipine besilate**, from Gedeon Richter Plc., in the therapeutic area of cardiovascular diseases;
- **Amlodipine besylate / valsartan / hydrchlorothiazide**, from Novartis Europharm Ltd., in the therapeutic area of cardiovascular diseases.

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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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.

Withdrawals
The PDCO noted that 6 applications, of which 2 were requests for modifications to agreed PIPs, were withdrawn during the late stages of the evaluation (30 days or less before opinion).

Interaction with external experts
The PDCO has regular interactions with academic experts, with a view to bringing state-of-the-art knowledge to the PDCO scientific discussions. Two experts were invited to the December meeting with a clinical expertise in paediatric neurology to discuss specific products intended to treat epilepsy and sleep disorders.

The next meeting of the PDCO will be held on 13-15 January 2010.

– END –

Notes:

1. PDCO opinions on PIPs and waivers are transformed into EMEA decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the EMEA website at: http://www.emea.europa.eu/htms/human/paediatrics/decisions.htm
2. 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 EEA, have to provide either the results of studies in children conducted in accordance with an approved PIP, or an EMEA decision on a waiver or on a deferral.
3. More information about the PDCO and the Paediatric Regulation is available in the 'Medicines for children' section of the EMEA website.
4. This meeting report, together with other information on the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

Enquiries only to: paediatrics@emea.europa.eu

Annex of the December 2009 PDCO meeting report

	2007 (August to December)	**2008** (January to December)	**2009** (January to current month)	**Cumulative total**
Total number of validated PIP/waiver applications	**85**	**271**	**273**	**629**[1]
Applications submitted for a product not yet authorised *(Article 7*[2]*)*	39	186	191	416 *(66%)*
Applications submitted for a product already authorised and still under patent, in view of a submission of a variation/extension for a new indication, pharmaceutical form or route of administration *(Article 8*[2]*)*	45	75	72	192 *(31%)*
Applications submitted for an off-patent product developed specifically for children with an age-appropriate formulation *(Article 30*[2]*)*	1	10	10	21 *(3%)*
PIPs and full waiver indications covered by these applications	**202**	**395**	**364**	**961**

Number of Paediatric Committee (PDCO) opinions	**2007**	**2008**	**2009**	**Cumulative total**
Positive on full waiver	10	48	67	125
Positive on PIP, including potential deferral	2	81	122	205
Negative opinions adopted	0	4	13	17
Positive opinions adopted on modification of a PIP	0	8	51	59
Positive opinions on compliance with a PIP	0	5	8	13
Negative opinions on compliance check with a PIP	0	0	1	1

[1] Of which 156 have been requests for a full waiver.
[2] Applications submitted in accordance with the referenced article of Regulation (EC) No 1901/2006, as amended.

Areas covered by PIPs/waiver applications	**2007** *(%)*	**2008** *(%)*	**2009** *(%)*
Neurology	12	6	4
Uro-nephrology	-	3	5
Gastroenterology-hepatology	9	3	2
Pneumology-allergology	8	6	6
Infectious diseases	12	8	9
Cardiovascular diseases	12	14	9
Diagnostics	-	1	1
Endocrinology-gynaecology-fertility-metabolism	19	15	16
Neonatology-paediatric intensive care	-	1	2
Immunology-rheumatology-transplantation	5	6	6
Psychiatry	5	3	3
Pain	1	3	6
Haematology-haemostaseology	1	5	6
Otorhinolaryngology	-	1	1
Oncology	11	12	11
Dermatology	1	3	6
Vaccines	2	6	4
Ophthalmology	1	2	2
Anaesthesiology	-	1	1
Nutrition	1	1	0