European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 July 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ILARIS

International Nonproprietary Name (INN): ***canakinumab***

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation under exceptional circumstances for the medicinal product Ilaris, 150 mg/ml, powder for solution for injection intended for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg.

Ilaris was designated as an orphan medicinal product on 20 March 2007. The applicant for this medicinal product is Novartis Europharm Ltd.
The active substance of Ilaris is canakinumab a human monoclonal anti-human interleukin-1β (IL-1β) antibody (L04AC04) that was designed to bind selectively to and neutralize the activity of IL-1β, a pro-inflammatory cytokine, which is produced mainly by mononuclear phagocytes in response to injury and infection.

The benefits with Ilaris are the reduction of inflammatory activity caused by neutralisation of excessively secreted IL-1 in CAPS, The most common side effects are infections, particularly of the upper respiratory tract, vertigo and injection site reactions.

A pharmacovigilance plan for Ilaris, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:
Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg, including:
- Muckle-Wells Syndrome (MWS),
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA),
- Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.

Treatment should be initiated and supervised by a specialist physician experienced in the diagnosis and treatment of CAPS.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Ilaris and therefore recommends the granting of the marketing authorisation under exceptional circumstances[***].

[***] Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.