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
ARCALYST

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

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 Arcalyst, 80 mg/ml, powder and solvent for solution for injection, ARCALYST is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults and children aged 12 years and older.

Arcalyst was designated as an orphan medicinal product on 10 July 2007. The applicant for this medicinal product is Regeneron UK Limited.

The active substance of Arcalyst is rilonacept, a dimeric fusion protein which acts by blocking IL-1β, a pro-inflammatory cytokine, which is produced mainly by mononuclear phagocytes in response to injury and infection.

The benefits with Arcalyst 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, headache and injection site reactions.

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

The approved indication is: treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) with severe symptoms, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children aged 12 years and older.

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.

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

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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.

[***] 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.

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