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

London, 25 June 2009
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**SUMMARY OF POSITIVE OPINION[*]**
**for**
**CAYSTON**

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

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,[**] recommending to grant a conditional marketing authorisation for the medicinal product Cayston, powder and solvent for nebuliser solution, 75 mg, intended for suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older. Cayston was designated as an orphan medicinal product on 21 June 2004. The applicant for this medicinal product is Gilead Sciences International Ltd.

The active substance of Cayston is aztreonam, an antibacterial medicinal product for inhalation use only (ATC code: J01DF01). Aztreonam binds to penicillin-binding proteins of susceptible bacteria, including P. aeruginosa, which leads to inhibition of bacterial cell wall synthesis, followed by cell lysis. The benefits with Cayston, based on a 28-day three times daily course of treatment, are its clinically relevant improvement of pulmonary function in adult patients with cystic fibrosis (CF) suffering from chronic pulmonary infection due to Pseudomonas aeruginosa. The most common side effects are wheezing, cough, non-allergic bronchospasm, rash and pyrexia.

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

The approved indication is: "Cayston is indicated for the suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older. The primary support for this indication is based on two single 28 day course placebo-controlled studies. The data to support the sustainability of the observed short term benefit over subsequent courses of treatment are limited (see section 5.1). Consideration should be given to official guidance on the appropriate use of antibacterial agents."

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 Cayston and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[***].

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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.

[***] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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