15 August 2012
EMA/CHMP/533490/2012
Committee for Medicinal Products for Human Use (CHMP)

Zerit

(stavudine)

Procedure No. EMEA/H/C/000110/A45/051

CHMP assessment report for paediatric use studies submitted according to Article 45 of the Regulation (EC) No 1901/2006

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted

Disclaimer: The assessment report was drafted before the launch of the European Medicines Agency's new corporate identity in December 2009. This report therefore has a different appearance to documents currently produced by the Agency.

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Rapporteur's Assessment Report for paediatric studies submitted in accordance with Article 45 of Regulation (EC) No1901/2006, as amended

Zerit (stavudine)

EMEA/H/C/110/P45/051

Marketing Authorisation Holder: Bristol-Myers Squibb Pharma

Rapporteur:	SE
Start of the procedure:	26/04/2009
Date of this report:	2009-06-10
Deadline for CHMP member's comments:	2009-06-11

ADMINISTRATIVE INFORMATION

Invented name of the medicinal product:	Zerit
INN (or common name) of the active substance(s):	stavudine
MAH:	Bristol-Myers Squibb Pharma
Currently approved Indication(s)	
Pharmaco-therapeutic group (ATC Code):	J05AF04
Pharmaceutical form(s) and strength(s):	Capsules 15, 20, 30, 40 mg, powder for injection 1 mg/ml

RECOMMENDATION

The MAH submitted two completed paediatric studies for Zerit, in accordance with Article 45 of the Regulation (EC) No 1901/2006, as amended on medicinal products for paediatric use.

These studies do not change the benefit-risk for the use of Zerit in paediatric patients, and are not relevant for the Summary of Product Characteristics.

Assessment

ACTG 338, performed in 1997-1998, randomized (1:1:1) 297 “clinically stable” children, treatment experienced but naïve to protease inhibitors, and with ongoing ART (unchanged for at least the last 4 months) to:

zidovudine + lamivudine *or*
stavudine (1 mg/kg bid) + full dose ritonavir *or*
Zidovudine+lamivudine + full dose ritonavir.

Efficacy in this trial is, naturally, of low interest today. No significant differences in worst degree of toxicity were noted between arms, and no deaths occurred.
(Study published in JAMA 2000, Jan 26;283(4):492-8.)

ACTG 366 was performed in 1998-2000, and included treatment experienced children and adolescents from the age of 6 months and with rapidly progressive HIV infection (n=200). Various regimens could be used, depending on treatment history, ie patients were not randomized to any specific combination of antiretrovirals. Stavudine was part of the regimen for around 60% of the patients.
(Study published in The Journal of Infectious Diseases 2005; 192:296–302)

Conclusion: Studies 338 and 366 do not add any relevant information regarding efficacy and safety of stavudine in paediatric patients.