18 February 2010
EMA/150112/2013
Committee for Medicinal Products for Human Use (CHMP)

# Celsentri

(maraviroc)

Procedure No. EMEA/H/C/000811/P46/0035

# CHMP assessment report for paediatric use studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

The company has, for formal reasons, submitted the final study report (up to week 48) of Study 1029, in accordance with article 46. This study was not a pediatric study, but included 4 (out of total 186) patients with an age of 16-18 years (the rest being 18 years and above). Study 1029 has no bearing with regards to article 46. No regulatory action is warranted in response to that report.

When approving the pediatric investigational plan it was agreed that it was not urgent to present pediatric studies for maraviroc, in particular not in the very youngest, having the mechanism of action (CCR5-inhibiton), and efficacy results in treatment naives (lower efficacy than control regimen) in mind.

According to websites the MAH is presently undertaking one study in children of ages 2-18 years old; in addition one academic study is also exploring maraviroc in combination with other recently approved antiretrovials, in children 6 years and older. Both studies are mainly focused on pharmacokinetics, and recruitment seems slow.