EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2010
EMA/339929/2009
Human Medicines Development and Evaluation

Report on the meeting of the Paediatric Human Immunodeficiency Virus (HIV) Expert Group, London 26 May 2009

Clinical trials in paediatric Human Immunodeficiency Virus (HIV)

Aim

A Paediatric Human Immunodeficiency Virus (HIV) Expert Group Meeting was held at the European Medicines Agency in London on 26 May 2009 to identify the best possible development approaches for existing and new medicines in the field of HIV in childhood and adolescence for Paediatric Investigation Plans.

Introduction

The aim of this meeting, i.e. the identification of the best possible **development approaches** for existing and new medicines in the field of HIV in childhood and adolescence for Paediatric Investigation Plans was emphasized and an outline of the current situation given.

This situation is mainly characterized by the number of different classes of medicines being investigated and to be investigated in the paediatric population, the different types of patient population (treatment-experienced, treatment-naïve patients, ethnic factors) and the epidemiology of the disease to be considered when planning trials in the paediatric population.

Conclusions

Patients population

1. **Treatment-naïve/treatment-experienced**

- The group acknowledged and agreed that efficacy can be extrapolated from the adult population to the paediatric population, and that dosage recommendations can be extrapolated from treatment-experienced patients to treatment-naive patients.
- The group did not consider acceptable to extrapolate from paediatric treatment-naive patients to treatment-experienced patients. It is therefore recommended to study a medicine first in the treatment-experienced population; starting in the naive-population is strongly discouraged.

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- Once the development has been performed in the experienced population, a minimum of naive-patients can be enrolled in order to perform modeling for the dose recommendations.
- With regards to the definition of treatment-experienced patients, the group agreed that for the paediatric population from birth to 18 years of age this is defined according to the resistance profile, whereas in adults it is defined according to the treatment background of the patients. Therefore a resistance test should be performed in the first month of life.
- The group agreed that children less than 12 months of age will have to be included in the paediatric studies, regardless of their background, to have a consistent approach and to obtain data in that age category, which is considered a priority. These children should therefore be enrolled in trials with both treatment-experienced and treatment-naive patients.

2. **Age groups**

- The expert group agreed that to separate the different age groups per Tanner stage might not be a practical way to proceed, unless the staggered approach is to be performed according to pubertal maturation; in this case it is important to separate the patients group per Tanner stage.

Epidemiology

- The group acknowledged that most available patients for large studies will be outside the EU and the USA. It was agreed that the quality and the standards of the trials must be closely monitored.
- The expert group agreed that results from Asian/African/South American populations can be extrapolated to the Caucasian population.

Classes of anti-HIV medicines

- The experts acknowledged that preclinical data strongly influenced the development in the paediatric population.
- With regards to the younger cohorts, the need for an age-appropriate formulation is necessary.
- Fixed-dose combination: it was agreed that it is essential to know the doses of independent classes in order to anticipate better the activity of the combination.
- With regard to new classes, the group agreed that PK and safety studies are considered acceptable; however data from comparative trials should be provided.
- It was agreed that although in general there might be no need to wait for results in adults before starting the studies in the paediatric population, for new classes a staggered approach starting with the older cohorts should be adopted.
- For new classes of medicines, the experts agreed on the need to have a pharmacovigilance database in order to collect adverse events following the administration.

List of participants:

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