



EMA/620746/2010

## Agenda –Expert meeting on paediatric asthma

20 October 2010, 9:00-15:30, meeting room 1A

Chairpersons: Daniel Brasseur / Irmgard Eichler

Item	Agenda	Topic leader	Time
	<b>Arrival and registration</b>		9:00- 9:30
1	Welcome address and conflict of interest Introduction of participants	Chairpersons	9:30- 9:40
2	Introduction and background	Irmgard Eichler / Janina Karres	9:40- 10:00
3	<b>Children 5 years and below - questions to discuss:</b> <ul style="list-style-type: none"><li>• Adequate definition of the paediatric target population: asthma phenotypes, atopic versus non-atopic, diagnostic criteria, inclusion and exclusion criteria.</li><li>• Is there a need to differentiate / stratify between viral induced wheezers and atopic wheezers?<ul style="list-style-type: none"><li>- Should they be studied separately?</li><li>- If yes, are separate trials feasible?</li></ul></li><li>• Cut-off age for including pre-school children in clinical trials:<ul style="list-style-type: none"><li>- From what age can “asthma” reliably be diagnosed?</li><li>- Should infants be included if the paediatric target population can be sufficiently defined?</li><li>- If yes, from what age (6 months, 1 year, 2 years)?</li></ul></li></ul>	N/A	10:00- 12:30



Item	Agenda	Topic leader	Time
	<p><b>Children 5 years and below - questions to discuss: (Cont.)</b></p> <ul style="list-style-type: none"> <li>• Choice of endpoint for different age-groups which is suitable to fulfil regulatory requirements: <ul style="list-style-type: none"> <li>- Assessment of asthma control in children - what validated tests are available? For what age ranges?</li> <li>- What surrogate endpoints and biomarkers could be used? Are they validated for all paediatric age subsets?</li> <li>- Definition of exacerbation in preschool children?</li> </ul> </li> <li>• How to evaluate efficacy in pres-school children? <ul style="list-style-type: none"> <li>- Is there a need to evaluate efficacy or could it be extrapolated?</li> <li>- How much could be extrapolated from adults to children for what types of medications?</li> <li>- How to evaluate treatment effect in infants/toddlers?</li> </ul> </li> </ul>		
	<p><b>Lunch</b></p>		<p>12:30- 13:15</p>
4	<p><b>Children above 5 years / general issues to discuss:</b></p> <ul style="list-style-type: none"> <li>• Are placebo-controlled trials justified? <ul style="list-style-type: none"> <li>- If yes, in what patient population/condition (episodic wheezing, mild-moderate asthma...)?</li> <li>- If not, in what patient population/condition (persistent asthma, moderate-severe asthma...)?</li> </ul> </li> <li>• Choice of active comparator: <ul style="list-style-type: none"> <li>- What comparator to be used for what disease severity (GINA recommendation)?</li> <li>- Need to differentiate between target population (e.g. ICS for "classic asthma" and montelukast for virus-induced episodic wheezing)?</li> </ul> </li> <li>• Is there a need to study dose-relationship in all age subsets in children or only for a specific age subset (e.g. the below 5 years of age)?</li> <li>• Is there a need for long-term safety and efficacy follow-up to evaluate impact of medicines on growth, development, maturation, bone, exacerbation rate? <ul style="list-style-type: none"> <li>- Where are the highest unmet needs; for what class of drugs?</li> <li>- For what age groups (below adolescent age range)?</li> <li>- For how long?</li> </ul> </li> </ul>	N/A	<p>13:15- 15:20</p>

Item	Agenda	Topic leader	Time
	<p><b>Children above 5 years / general issues to discuss: (Cont.)</b></p> <ul style="list-style-type: none"> <li>• Exercise induced asthma/bronchoconstriction in paediatric population: <ul style="list-style-type: none"> <li>- Need for separate studies?</li> <li>- If yes: what should be the efficacy endpoint?</li> <li>- How to assess treatment effect in infants and toddlers?</li> </ul> </li> <li>• Place of specific immunotherapy in allergic asthma. <ul style="list-style-type: none"> <li>- Is there a need to evaluate impact of specific immunotherapy on asthma control?</li> <li>- If yes, what should be the efficacy endpoint: Asthma control? Lung function? Dose of controller medication?</li> </ul> </li> </ul>		
5	<b>Summary and closing of the meeting</b>	Chairpersons	15:20-15:30