c4c Multi-Stakeholder Meeting on Paediatric Atopic Dermatitis (AD)

1 - 2 March 2022
Virtual event

Summary

The second International conect4children Multi-Stakeholder Meeting on Atopic Dermatitis in children and adolescents took place virtually on 1 and 2 March 2022 with the participation of more than 100 attendees from 20 countries (Europe and US) representing young patients and advocates, clinicians, academics and researchers, pharmaceutical companies and regulators (EMA, FDA)/NoBos/policymakers.

The concept of a Multi-Stakeholder Meetings is to facilitate dialogue and provide an opportunity for constructive interactions among all relevant stakeholders on topics requiring open discussion on development of medicines in the best interests of children and adolescents. No regulation decisions are made during the meeting and only publicly available information are shared. The value of such meetings has been demonstrated in paediatric oncology by ACCELERATE in the recent years.

The overarching objective of the meeting was to propose a strategy to improve the timely development of therapeutic innovations for children and adolescents with AD, properly addressing paediatric unmet needs through science, introducing innovative development pathways and increasing accessibility for all patients. The goal was to set up a cooperation of academia and industry, with support of advocacy and regulators within a new and facilitating regulatory environment.

Through updating the biology and scientific rationale for drug development in AD, defining the unmet medical needs of children and adolescents with AD, hearing the voices of patients and parents coping with the disease, and sharing public updates of ongoing paediatric and adult drug development, the meeting discussed and addressed the following crucial points/questions:

- How to best address the unmet needs of children and develop safe and effective therapies for all, that are also accessible and affordable?
- How to improve trials in children (best trial designs, use of surrogate endpoints, reduced number of patients to be enrolled, extrapolation from adult data, improve trial execution)?
- How to accelerate the developments in children and set up prioritization among assets in development when needed?
- Lack of biomarkers and the current research thereof in AD.
- How to define the strategic use of new medicines to better address paediatric patients' needs and journeys?
    - How to identify early in their disease patients who have or will develop moderate or severe AD and be candidates for innovative therapies?
    - How to position novel systemic treatments in the life-long journey of young people living with AD e.g., when to start and when to stop (or not stop)?
    - How to weigh up the choice of treatment regarding comorbidities, e.g. anti-IL4Rα/IL13 in those with comorbid asthma.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389.
The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

The meeting offered a unique opportunity to share and discuss all recent advances and progress in the field of paediatric AD, to review and discuss molecules with an ongoing paediatric development plan. New development pathways introducing alternative innovative trial designs and pharmacological evaluation, concrete use of extrapolation, use of real-world data and earlier initiation of paediatric studies will be defined.

This successful meeting showed the potential value of multi-stakeholder discussion and working together in paediatric fields other than oncology.

Following the meeting conclusions, a joint article will be submitted to a peer reviewed journal in the specialty.

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