Overview of Paediatric Investigation Plans for uveitis

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Voclosporin

**Active substance(s):**
Voclosporin

**Condition(s):**
Chronic non-infectious uveitis

**Pharmaceutical form(s):**
Soft capsules
Oral liquid

**Route(s) of administration:**
Oral use

**Name/corporate name of the PIP applicant:**
Lux Biosciences GmbH
Voclosporin - agreed measures

Development of an oral liquid formulation

Juvenile animal toxicity study
Open-label, multi-centre, dose-titration study of voclosporin for the treatment of non-infectious uveitis in children from 6 years to less than 18 years of age.

Open-label, multi-centre study to evaluate safety and efficacy of voclosporin for the treatment of non-infectious uveitis in children from 6 years to less than 18 years of age.

Multi-centre study to assess the safety and efficacy of voclosporin in the treatment of non-infectious uveitis in children from 2 to less than 6 years of age.
AIN457

**Active substance(s):**
Recombinant human monoclonal antibody to human Interleukin 17A (AIN457)

**Condition(s):**
Treatment of chronic non-infectious uveitis

**Pharmaceutical form(s):**
Powder for solution for injection

**Route(s) of administration:**
Subcutaneous use

**Name/corporate name of the PIP applicant:**
Novartis Europharm Limited
AIN457 – agreed measure

A double-blind, randomised, placebo-controlled, multicentre, dose ranging trial with AIN457 in paediatric population with active chronic non-infectious uveitis
JIA uveitis

• No separate studies agreed yet for biologics
• Uveitis exclusion from JIA studies?
• Conclusion of paediatric rheumatology expert meetings (no exclusion)
• Inclusion into JIA studies or separate studies for JIA uveitis?
Treatment response - activity of uveitis

**Inactive**
Grade 0 cells

**Worsening activity**
Two-step increase in level of inflammation (e.g. anterior chamber cells, vitreous haze) or increase from grade 3+ to 4+

**Improved activity**
Two-step decrease in level of inflammation (e.g. anterior chamber cells, vitreous haze) or decrease to grade 0

**Remission**
Inactive disease for >3 months after discontinuing all treatments for eye disease

*(Standardisation of uveitis nomenclature, SUN, 2005)*
Potential endpoints for clinical studies

- Change in either anterior chamber cells or vitreous haze
- Achieving quiescence (cell grade or haze)
- Combination of achieving quiescence, visual acuity change and change in concomitant medication
- Combination of SUN criteria, concomitant medication and quality of life
- In JIA combination of local findings with JIA core set criteria