EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Inflammatory bowel disease (IBD)

Overview of the Paediatric investigation plans

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Adalimumab - Crohn’s disease

- **Indication:**
- Treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.
- **The waiver applies to:**
- Paediatric population from birth to **less than 6 years** of age for solution for injection for subcutaneous use
- on the grounds that the disease or condition for which the specific medicinal product is intended **does not occur** in the specified paediatric subset(s)

Adalimumab - Crohn’s disease

Studies:

•A Multi-centre, Double-blind (DB) Study to Evaluate the Safety, Efficacy and Pharmacokinetics (PK) of the Human Anti-TNF Monoclonal Antibody Adalimumab in Paediatric Patients with Moderate to Severe Crohn's Disease (CD).

•A Multi-centre, Open-label (OL) Study of the Human Anti-TNF Monoclonal Antibody Adalimumab to Evaluate the Efficacy and the Long-term Safety and Tolerability of Repeated Administration of Adalimumab in Paediatric Patients with Crohn's Disease (CD) Who Have Demonstrated a Clinical Response in a Controlled Double-blind Study.

Adalimumab – Ulcerative colitis

The waiver applies to:

children from birth to **less than 4 years**

for solution for injection in pre-filled syringe, subcutaneous use

on the grounds that the disease or condition for which the specific medicinal product is intended **does not occur** in the specified paediatric subset(s).

Adalimumab – Ulcerative colitis

Studies:

1. Modelling and simulation study – exposure response analysis for dose selection in study 2.

2. Multicentre, **randomised,double-blind, three arm,** lower and higher dose, **placebo-controlled** trial to evaluate the efficacy, safety and pharmacokinetics of adalimumab in children from 4 to less than 18 years of age with moderately to severely active ulcerative colitis

3. Multi-centre, open-label study to evaluate the efficacy and the long-term safety and tolerability of adalimumab in children from 4 to less than 18 years of age with moderately to severely active ulcerative colitis

Infliximab – Crohn's disease

Indication:

Treatment of **severe**, active Crohn's disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies.

The waiver applies to:

Children from birth to less than 6 years on the grounds that the specific medicinal product is likely to be unsafe.

Children from 6 to less than 18 years on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

Infliximab – Crohn's disease

Indication:

Treatment of **moderate** Crohn's disease

The waiver applies to:

Children from birth to less than 18 years

on the grounds that the specific medicinal product **is likely to be unsafe.**

Infliximab – Ulcerative colitis

Indication:

Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.

The waiver applies to:

Children from birth to **less than 2 years** on the grounds that the disease or condition for which the specific medicinal product is intended **does not occur** in the specified paediatric subset(s).

Vedolizumab – CD+UC

The waiver applies to:

Children from birth to **less than 4 years**

on the grounds that the specific medicinal product is likely to **be unsafe**.

Vedolizumab – CD+UC

Study 1

Dose-ranging study to determine the pharmacokinetics, pharmacodynamics, safety, and tolerability of vedolizumab in paediatric patients with inflammatory bowel disease

Study 2

Randomised, double-blind, **placebo-controlled** two-dose, **three-arm**, multicenter study of the induction and maintenance of clinical response and remission by vedolizumab in paediatric patients with moderate to severe Crohn's disease

Study 3

Randomised, double-blind, **placebo-controlled** two-dose, **three-arm**, multicenter study of the induction and maintenance of clinical response and remission by vedolizumab in paediatric patients with moderate to severe ulcerative colitis