

Oral presentation

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## 2.3 Long-term efficacy and safety of infliximab plus methotrexate for the treatment of polyarticular course juvenile rheumatoid arthritis (JRA): Findings from an open-label treatment extension

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We report long-term safety & efficacy of infliximab (IFX)+methotrexate (MTX) treatment in JRA patients. In an international, multicenter, randomized, double-blind study, 122 children w/active polyarticular JRA despite prior MTX therapy received MTX plus a 3-dose induction (wks 0, 2, 6) of IFX 3 mg/kg through wk 44, or placebo (PBO) for 14 wks followed by IFX 6 mg/kg (wks 14, 16, 20, & then q8 wks) through wk 44. Patients completing treatment through wk 44 were eligible to enter an open-label extension (OLE) of IFX 3 mg/kg, beginning at wk 52 & continuing q8 wks through wk 196. All patients continued with concomitant MTX. Physicians could increase or decrease the IFX dose by  $\leq 1.5$  mg/kg/infusion q8 wks, up to 6 mg/kg or down to 3 mg/kg, based on clinical response. Primary endpoint was the proportion of patients meeting ACR-Pedi-30, defined as improvement of  $\geq 30\%$  in  $\geq 3$  of 6 core variables, &  $\leq 1$  of the remaining variables worsened by  $>30\%$ . Remission was defined as 0 joints with active

arthritis, normal ESR, & physician's global assessment  $\leq 10$  mm on a 10-cm visual analog scale. 78/122(63.9%) children entered the OLE. The mean(SD) IFX dose at wk 196 was 4.4(1.6)mg/kg. IFX was well-tolerated;14.1% of patients discontinued due to adverse events (AE) from wks 52–204. The distribution/types of AE were similar to those in the first 52 wks & no new safety issues were reported. Among the 36 study patients by wk 204, ACR-Pedi-30/50/70/90 responses were 91.7%(33/36), 83.3%(30/36), 69.4%(25/36), & 50%(18/36), respectively. 39%(14/36) of patients achieved remission. From wk 52 through wk 216, 36.6%(26/71) of patients were positive for IFXantibodies; 57.7%(15/26) of these had an infusion reaction. Continuous IFX+MTX administered up to 4 yrs was safe & effective in JRA patients, although accompanied by a high rate of patient discontinuation, which included subjects in remission.