277. GROWTH DURING TOCILIZUMAB THERAPY IN PATIENTS WITH POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS: 2-YEAR DATA FROM THE PHASE III CHERISH TRIAL

Athimalaipet Ramanan1,2, Kamal N. Bharucha3, Hermine I. Brunner4, Nicola Ruperto5, David A. Cabral4, Abraham Gedalia1, Valeria Gerloni5, Christian Jorgensen5, Daniel J. Lovell4, Alberto Martini5, Jim Frane6, Chris Wells7 and Fabrizio De Benedetti8

1 Paediatric Rheumatology, Bristol Royal Hospital for Children, Bristol, UK, 2 Royal National Hospital for Rheumatic Diseases, Bath, UK, 3 Medical Department, Genentech, South San Francisco, CA, 4 Pediatric Rheumatology Collaborative Study Group, PRCSG, Cincinnati, OH, USA, 5 Paediatric Rheumatology International Trials Organisation, Genoa, Italy, 6 Consultant, Rheumatology Department, Santa Monica, CA, USA, 7 Medical Department, Roche Products Ltd, Welwyn Garden City, UK and 8 Department of Pediatric Medicine, IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy

Background: In patients with JIA, elevated IL-6 levels have been associated with low growth velocity. The efficacy of tocilizumab (TCZ), an IL-6 receptor inhibitor, in patients with polyarticular-course JIA (pcJIA) has been demonstrated up to 104 weeks (2 years) in the phase III CHERISH trial. In CHERISH, growth was evaluated in patients with pcJIA treated with TCZ, with data available for up to 2 years on treatment.

Methods: In CHERISH patients with active pcJIA for ≥6 months and inadequate responses to MTX received open-label (OL) TCZ intravenously every 4 weeks [randomly assigned 1:1 to receive 8 or 10 mg/kg for body weight (BW) < 30 kg or 8 mg/kg for BW ≥30 kg] for 16 weeks. At week 16, patients with ≥JIA ACR30 response were randomly assigned 1:1 to receive placebo or to continue TCZ double-blind for 24 weeks. At week 40, all patients entered an OL extension and received TCZ according to BW through week 104. In patients with Tanner stage <4 (the subset of patients with the highest growth potential), height velocity and height S.D. scores (SDS) were measured, unless patients were receiving the growth hormone somatotropin during the study period.

Results: From 188 patients receiving ≥1 dose of TCZ, 123 patients with Tanner stage <4 were included in the growth population (1 patient received somatotropin and was excluded from the growth population). At baseline, the growth population had a mean World Health Organization height SDS (S.D.) of -0.5 (1.2). Baseline height SDS was not related to patient age or disease duration (Spearman’s rank correlations r = 0.08 and r = -0.12, respectively). For patients with Tanner stage <4 at baseline and height data at year 2 (n = 103), baseline mean height SDS increased significantly (by 0.40) from baseline to year 2 of treatment (P < 0.0001 vs baseline). At year 2, 71.8% (74/103) of these patients had an increased height SDS compared with their baseline height SDS. The mean height velocity in patients with Tanner stage <4 at baseline and height data at year 2 was 6.7 (2.0) cm/year (n = 103). For patients with available data at year 2 (n = 103), the mean daily oral CS doses (S.D.) at baseline and year 2 of treatment were 0.05 mg/kg (0.08) and 0.02 mg/kg (0.05), respectively.

Conclusion: At baseline, the mean height SDS of patients with pcJIA was below normal. The majority of patients (71.8%) who were Tanner stage <4 at baseline and who received TCZ for up to 104 weeks, had an increased height SDS at year 2 (the end of the study).

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