



## P019 - MAINTENANCE OF CLINICAL RESPONSE IN INDIVIDUAL CHILDREN WITH JUVENILE IDIOPATHIC ARTHRITIS TREATED WITH SUBCUTANEOUS ABATACEPT

I. Calvo Penadés<sup>1</sup>, N. Ruperto<sup>2</sup>, H. Brunner<sup>3</sup>, N. Tzaribachev<sup>2</sup>, I. Louw<sup>2</sup>, F. Zapata<sup>4</sup>, G. Horneff<sup>2</sup>, I. Foeldvari<sup>2</sup>, D. Kingsbury<sup>3</sup>, R. Joos<sup>2</sup>, M.E. Paz Gastanaga<sup>2</sup>, C. Wouters<sup>2</sup>, J. Breedt<sup>2</sup>, T. Lutz<sup>2</sup>, T. Miraval<sup>2</sup>, N. Rubio<sup>2</sup>, Y. Elbez<sup>5</sup>, M. Nys<sup>6</sup>, R. Wong<sup>7</sup>, A. Martini<sup>2</sup> and D.J. Lovell<sup>3, poi</sup>

<sup>1</sup>Hospital Universitario y Politécnico La Fe. Valencia. <sup>2</sup>PRINTO. Istituto Gaslini. Genoa (Italy). <sup>3</sup>PRCSG. CHMC Cincinnati (USA). <sup>4</sup>PRINTO. Star Medica Hospital. Mérida Yucatán (México). <sup>5</sup>Excelya. Boulogne-Billancourt (France). <sup>6</sup>Bristol-Myers Squibb. Braine-L'Alleud (Belgium). <sup>7</sup>Bristol-Myers Squibb. Princeton. NJ (USA).

### Resumen

**Introduction:** The efficacy of SC abatacept (ABA) in patients (pts) with polyarticular-course juvenile idiopathic arthritis (pJIA) was shown in a 2-year (yr), Phase III, open-label international study (NCT01844518). However, it is unknown whether each individual pt within a treatment group consistently achieves the same efficacy endpoint at all time points.

**Objectives:** To investigate whether ABA efficacy is maintained by individual pts with pJIA over time.

**Methods:** In this subgroup analysis, pts in two age cohorts (2-5 yrs and 6-17 yrs) who achieved clinical response to weekly SC ABA (10 to < 25 kg [50 mg], 25 to < 50 kg [87.5 mg], ≥ 50 kg [125 mg]) at Day 113 (time point of primary pharmacokinetics endpoint<sup>1</sup>) were followed for 2 yrs. Stringent efficacy outcomes selected for analysis included JIA-ACR70, JIA-ACR100, Juvenile Arthritis Disease Activity Score 71 (JADAS71) minimal disease activity (MDA; ≤ 3.8) and JADAS71 inactive disease (ID; ≤ 1) rates. Prognostic factors for sustained response were investigated using logistic regression.

**Results:** A total of 219 pts entered the study (46 [21.0%] 2-5 yrs; 173 [79.0%] 6-17 yrs) and a subgroup of these pts achieved a clinical response at Day 113 (Table 1). Most pts who achieved JIA-ACR70, JIA-ACR100, JADAS71 MDA and JADAS71 ID at Day 113 sustained their response at Day 393 and at Days 393 and 645 in the 2-5-yr and 6-17-yr cohorts (Table 2). Across cohorts, more than 75% and 60% of pts maintained a JIA-ACR 70 and JADAS71 MDA response through Day 645, respectively. Prior biologic (b)DMARD use was an important prognostic factor. In pts aged 6-17 yrs, sustained JIA-ACR70 response rate at Days 393 and 645 was 81% (57/70) in pts who did not have prior bDMARDs vs 57% (12/21) in pts who had prior bDMARDs (p = 0.0715); sustained JADAS71 MDA response rate was 71% (37/52) vs 37% (7/19; p = 0.0320). Prognostic factors for JIA-ACR100 response and JADAS71 ID in pts aged 6-17 yrs and for all outcomes in pts aged 2-5 yrs could not be determined due to low pt numbers.

Table 1. Proportion of pts who achieved a clinical response at Day 113

| Endpoint    | Pts with response at Day 113 |                  |
|-------------|------------------------------|------------------|
|             | 2-5 yrs (n = 46)             | 6-17 y (n = 173) |
| JIA-ACR70   | 34 (74)                      | 91 (53)          |
| JIA-ACR100  | 19 (41)                      | 25 (15)          |
| JADAS71 MDA | 28 (61)                      | 71 (41)          |
| JADAS71 ID  | 17 (37)                      | 28 (16)          |

Data are expressed as n (%). ID: inactive disease; JADAS71: Juvenile Arthritis Disease Activity Score 71; MDA: minimal disease activity; pt: patient; yr: year.

Table 2. Proportion of responders at Day 113 with sustained clinical response at Day 393, and at Days 393 and 645 in cohort aged 2-5 yrs and cohort aged 6-17 yrs

|         | 2-5-yr-old pts who achieved a clinical response at Day 113 |                     |                      |                     | 6-17-yr-old pts who achieved a clinical response at Day 113 |                     |                      |                     |
|---------|--|---------------------|----------------------|---------------------|---|---------------------|----------------------|---------------------|
|         | JIA-ACR70 (n = 34)   | JIA-ACR100 (n = 19) | JADAS71 MDA (n = 28) | JADAS71 ID (n = 17) | JIA-ACR70 (n = 91)  | JIA-ACR100 (n = 25) | JADAS71 MDA (n = 71) | JADAS71 ID (n = 28) |
| Day 393 | 32 (94)  | 12 (63)             | 25 (89)              | 10 (59)             | 78 (86)   | 20 (80)             | 58 (82)              | 21 (75)             |
| Day 645 | 32 (94)  | 11 (58)             | 23 (82)              | 9 (53)              | 69 (76)   | 15 (60)             | 44 (62)              | 18 (64)             |

Data are expressed as n (%). ID: inactive disease; JADAS71: Juvenile Arteritis Disease Activity Score 71; MDA: minimal disease activity; pt: patient; yr: year.

**Conclusions:** The majority of individuals with pJIA who achieved stringent efficacy endpoints with weekly SC abatacept by Day 113 sustained that clinical endpoint over time. Prior bDMARD use may be a prognostic factor for sustained response over 2 yrs.

Código EUDRACT: NCT01844518.

## References

1. Brunner HI, et al. Arthritis Rheumatol. 2018;70:1144-54. Abstract presented at EULAR 2019. Published in Ann Rheum Dis. 2019. DOI: 10.1136/annrheumdis-2019-eular.236.