**Supplementary Information**

**Supplementary Table 1 – Data for Fig. 1: Proportion of responders for (A) ACR20, (B) ACR50 and (C) ACR70 over time for the tofacitinib 5 and 10 mg BID groups in the efficacy subpopulation (FAS, observed).**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Tofacitinib 5 mg BID | | | Tofacitinib 10 mg BID | | |
|  | *N* | ACR response (%) | SE | *N* | ACR response (%) | SE |
| ***ACR20*** |  |  |  |  |  |  |
| *Month 1* | 32 | 75.0 | 7.7 | 31 | 74.2 | 7.9 |
| *Month 3* | 33 | 66.7 | 8.2 | 30 | 76.7 | 7.7 |
| *Month 6* | 31 | 74.2 | 7.9 | 29 | 86.2 | 6.4 |
| *Month 9* | 18 | 66.7 | 11.1 | 17 | 82.4 | 9.3 |
| *Month 12* | 17 | 82.4 | 9.3 | 16 | 93.8 | 6.1 |
| *Month 15* | 6 | 100.0 | 0.0 | 9 | 88.9 | 10.5 |
| *Month 18* | 6 | 66.7 | 19.2 | 9 | 77.8 | 13.9 |
| *Month 21* | 6 | 66.7 | 19.2 | 7 | 85.7 | 13.2 |
| *Month 24* | 6 | 100.0 | 0.0 | 6 | 83.3 | 15.2 |
| ***ACR50*** |  |  |  |  |  |  |
| *Month 1* | 32 | 21.9 | 7.3 | 31 | 41.9 | 8.9 |
| *Month 3* | 33 | 48.5 | 8.7 | 30 | 53.3 | 9.1 |
| *Month 6* | 31 | 51.6 | 9.0 | 29 | 65.5 | 8.8 |
| *Month 9* | 18 | 55.6 | 11.7 | 17 | 64.7 | 11.6 |
| *Month 12* | 17 | 52.9 | 12.1 | 16 | 75.0 | 10.8 |
| *Month 15* | 6 | 66.7 | 19.2 | 9 | 77.8 | 13.9 |
| *Month 18* | 6 | 33.3 | 19.2 | 9 | 66.7 | 15.7 |
| Month 21 | 6 | 33.3 | 19.2 | 7 | 71.4 | 17.1 |
| Month 24 | 6 | 83.3 | 15.2 | 6 | 83.3 | 15.2 |
| ***ACR70*** |  |  |  |  |  |  |
| *Month 1* | 32 | 3.1 | 3.1 | 31 | 9.7 | 5.3 |
| *Month 3* | 33 | 21.2 | 7.1 | 30 | 20.0 | 7.3 |
| *Month 6* | 31 | 25.8 | 7.9 | 29 | 24.1 | 8.0 |
| *Month 9* | 18 | 38.9 | 11.5 | 17 | 35.3 | 11.6 |
| *Month 12* | 17 | 41.2 | 11.9 | 16 | 43.8 | 12.4 |
| *Month 15* | 6 | 50.0 | 20.4 | 9 | 44.4 | 16.6 |
| *Month 18* | 6 | - | - | 9 | 44.4 | 16.6 |
| *Month 21* | 6 | 16.7 | 15.2 | 7 | 28.6 | 17.1 |
| *Month 24* | 6 | 16.7 | 15.2 | 6 | 33.3 | 19.2 |

ACR20/50/70: American College of Rheumatology 20/50/70 response rates; BID: twice daily; CI, confidence interval; FAS: full analysis set; SE, standard error.

N represents the numbers of patients with non-missing ACR response.

Efficacy analyses were based on three studies: ORAL Scan, ORAL Solo and ORAL Sync.

**Supplementary Table 2 – Data for Fig. 2: Mean DAS28-4(ESR) over time for the tofacitinib 5 and 10 mg BID groups in the efficacy subpopulation (FAS, observed).**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Tofacitinib 5 mg BID | | | Tofacitinib 10 mg BID | | |
|  | *N* | Mean | SE | *N* | Mean | SE |
| *Baseline* | 33 | 6.3 | 0.1 | 31 | 6.2 | 0.2 |
| *Month 1* | 2 | 4.6 | 0.8 | 6 | 4.0 | 0.7 |
| *Month 3* | 33 | 4.3 | 0.2 | 30 | 3.9 | 0.2 |
| *Month 6* | 30 | 3.9 | 0.2 | 29 | 3.6 | 0.3 |
| *Month 9* | 6 | 4.2 | 0.4 | 10 | 3.1 | 0.4 |
| *Month 12* | 17 | 3.7 | 0.3 | 16 | 2.8 | 0.2 |
| *Month 15* | 6 | 3.4 | 0.3 | 9 | 2.8 | 0.4 |
| *Month 18* | 6 | 4.6 | 0.7 | 9 | 2.9 | 0.4 |
| *Month 21* | 6 | 4.1 | 0.2 | 7 | 3.2 | 0.5 |
| *Month 24* | 5 | 4.0 | 0.2 | 6 | 2.7 | 0.6 |

BID: twice daily; DAS28-4(ESR): Disease Activity Score-erythrocyte sedimentation rate; FAS: full analysis set; SE: standard error.

N represents the numbers of patients with non-missing DAS28-4(ESR).

Efficacy analyses were based on three studies: ORAL Scan, ORAL Solo and ORAL Sync.

**Supplementary Table 3 – Data for Fig. 3: Change from baseline in HAQ-DI over time for the tofacitinib 5 and 10 mg BID groups in the efficacy subpopulation (FAS, observed).**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Tofacitinib 5 mg BID | | | Tofacitinib 10 mg BID | | |
|  | *N* | Mean change from baseline | SE | *N* | Mean change from baseline | SE |
| *Month 1* | 32 | –0.4 | 0.1 | 31 | –0.9 | 0.1 |
| *Month 3* | 33 | –0.6 | 0.1 | 30 | –0.9 | 0.1 |
| *Month 6* | 31 | –0.8 | 0.1 | 29 | –0.9 | 0.1 |
| *Month 9* | 18 | –1.0 | 0.2 | 17 | –0.9 | 0.2 |
| *Month 12* | 17 | –1.0 | 0.2 | 16 | –0.8 | 0.2 |
| *Month 15* | 6 | –0.8 | 0.2 | 9 | –0.6 | 0.3 |
| *Month 18* | 6 | –0.7 | 0.3 | 9 | –0.8 | 0.3 |
| *Month 21* | 6 | –0.8 | 0.3 | 7 | –0.7 | 0.3 |
| *Month 24* | 6 | –0.9 | 0.3 | 6 | –1.0 | 0.2 |

BID: twice daily; FAS: full analysis set; HAQ-DI: Health Assessment Questionnaire-Disability Index; SE: standard error.

N represents the numbers of patients with non-missing HAQ-DI.

Efficacy analyses were based on three studies: ORAL Scan, ORAL Solo and ORAL Sync.

**Supplementary Table 4 – Study Dates and Principal Investigator Details**

|  |  |  |
| --- | --- | --- |
| **Study** | **Study Initiation/Completion Dates** | **Principal Investigator** |
| ORAL Scan (NCT00847613) (31) | March 2009/ February 2012 | Dr. William José Otero Escalante: Santander, Colombia; Dr. Javier Darío Márquez Hernández: Antioquia, Colombia; Dr. Edwin Antonio Jauregui (previous Principal Investigator), Dr María Concepción Maldonado: Cundinamarca, Colombia; Dr. Juan José Jaller Raad: Atlántico, Colombia; |
| ORAL Sync (NCT00856544) (30) | May 2009/ January 2011 | Dr. William José Otero Escalante: Santander, Colombia;  Dr. Juan José Jaller Raad: Atlántico, Colombia; Dr Edwin Antonio Jauregui (previous Principal Investigator), Dr María Concepción Maldonado: Cundinamarca, Colombia; |
| ORAL Solo (NCT00814307) (29) | February 2009/ June 2010 | Dr. William José Otero Escalante: Santander, Colombia; Dr. Juan José Jaller Raad: Atlántico, Colombia; |
| ORAL Start (NCT01039688) (33) | January 2010/ March 2013 | Dr. Edgardo David Tobias (previous Principal Investigator), Dr. Patricia Julieta Vélez-Sánchez: Cundinamarca, Colombia; Dr. Juan José Jaller Raad: Atlántico, Colombia; Dr. William José Otero Escalante: Santander, Colombia; |