**ONLINE SUPPLEMENTARY MATERIAL**

**Anifrolumab effects on rash and arthritis: impact of the type I interferon gene signature on single-manifestation results in the phase IIb MUSE study in patients with systemic lupus erythematosus**

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**Table 1.** List of most common manifestations, as measured by SLEDAI-2K, in patients from the phase IIb MUSE study.

|  |
| --- |
| **Baseline involvement (SLEDAI-2K)** |
| **SLEDAI-2K manifestation** | **Patients, %** |
| Arthritis | 96.4 |
| Rash | 84.6 |
| Alopecia | 75.7 |
| Low complement | 45.2 |
| Mucosal ulcers | 43.3 |
| Increased DNA | 25.9 |
| Vasculitis | 8.2 |
| Leukopenia | 7.2 |
| Proteinuria | 6.6 |
| Pleurisy | 4.6 |
| Fever | 3.9 |
| Haematuria | 3.0 |
| Pyuria | 3.0 |
| Myositis | 2.3 |
| Pericarditis | 2.3 |
| Lupus headache | 0.7 |
| Thrombocytopenia | 0.7 |
| Organic brain syndrome | 0.3 |

SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.

**Table 2.** mCLASI in patients entering the phase IIb MUSE study with a score ≥6 or a score ≥10 at week 52.

|  |  |  |  |
| --- | --- | --- | --- |
|  | All patients | IFNGS test–high subgroup | IFNGS test–low subgroup |
|  | PlaceboN=102 | Anifrolumab 300 mg Q4WN=99 | PlaceboN=76 | Anifrolumab 300 mg Q4WN=75 | PlaceboN=26 | Anifrolumab 300 mg Q4WN=24 |
| mCLASI activity score ≥6 at baseline |  |  |  |  |  |  |
| Patients with baseline  involvement, n | 35 | 39 | 32 | 34 | 3 | 5 |
| Patients with improvement, n (%)a | 12 (34.3) | 21 (53.8) | 11 (34.4) | 19 (55.9) | 1 (33.3) | 2 (40.0) |
| OR (90% CI) |  | 2.27 (1.02, 5.03) |  | 2.47 (1.06, 5.73) |  | 1.57 (0.06, 42.30) |
| p value  |  | 0.091 |  | 0.078 |  | 0.820 |
| mCLASI activity score ≥10 at baseline |  |  |  |  |  |  |
| Patients with baseline  involvement, n | 23 | 23 | 23 | 23 | 0 | 0 |
|  Patients with improvement, n (%)a | 7 (30.4) | 13 (56.5) | 7 (30.4) | 13 (56.5) | 0 | 0 |
| OR (90% CI) |  | 2.91 (1.04, 8.09) |  | 2.91 (1.04, 8.09) | NA | NA |
| p value |  | 0.086 |  | 0.086 | NA | NA |

aPatients who achieved ≥50% improvement from baseline.

IFNGS, interferon gene signature; mCLASI, modified Cutaneous Lupus Erythematosus Disease Area and Severity Index; NA, not applicable; Q4W, every 4 weeks.

**Table 3.** Effect of anifrolumab 1000 mg on rash and arthritis versus placebo at week 52.

|  |  |  |  |
| --- | --- | --- | --- |
|  | All patients | IFNGS test–high subgroup | IFNGS test–low subgroup |
|  | PlaceboN=102 | Anifrolumab 1000 mg Q4WN=104 | PlaceboN=76 | Anifrolumab 1000 mg Q4WN=78 | PlaceboN=26 | Anifrolumab 1000 mg Q4WN=26 |
| Rash measured by SLEDAI-2K |  |  |  |  |  |  |
| Patients with baseline  involvement, n | 88 | 82 | 65 | 61 | 23 | 21 |
| Patients with resolution, n (%) | 13 (14.8) | 23 (28.0) | 7 (10.8) | 18 (29.5) | 6 (26.1) | 5 (23.8) |
| OR (90% CI) |  | 2.30 (1.21, 4.38) |  | 3.50 (1.56, 7.82) |  | 1.14 (0.34, 3.82) |
| p value  |  | 0.033 |  | 0.011 |  | 0.859 |
| Rash measured by BILAG |  |  |  |  |  |  |
| Patients with baseline  involvement, n | 85 | 74 | 64 | 54 | 21 | 20 |
|  Patients with improvement, n (%) | 24 (28.2) | 28 (37.8) | 17 (26.6) | 21 (38.9) | 7 (33.3) | 7 (35.0) |
| OR (90% CI) |  | 1.59 (0.91, 2.79) |  | 1.81 (0.94, 3.49) |  | 1.30 (0.42, 4.03) |
|  p value |  | 0.175 |  | 0.139 |  | 0.704 |
| mCLASI |  |  |  |  |  |  |
| Patients with baseline involvement, n | 89 | 84 | 67 | 62 | 22 | 22 |
|  Patients with improvement, n (%)a | 30 (33.7) | 42 (50.0) | 21 (31.3) | 31 (50.0) | 9 (40.9) | 11 (50.0) |
|  OR (90% CI) |  | 2.02 (1.20, 3.41) |  | 2.27 (1.24, 4.17) |  | 1.50 (0.53, 4.24) |
|  p value |  | 0.026 |  | 0.027 |  | 0.519 |
| Arthritis measured by SLEDAI-2K |  |  |  |  |  |  |
| Patients with baseline involvement, n | 99 | 98 | 73 | 72 | 26 | 26 |
|  Patients with  resolution, n (%) | 42 (42.4) | 49 (50.0) | 29 (39.7) | 36 (50.0) | 13 (50.0) | 13 (50.0) |
|  OR (90% CI) |  | 1.40 (0.87, 2.25) |  | 1.59 (0.91, 2.78) |  | 1.01 (0.40, 2.53) |
| p value |  | 0.249 |  | 0.173 |  | 0.992 |
| Arthritis measured by BILAG |  |  |  |  |  |  |
| Patients with baseline  involvement, n | 95 | 91 | 72 | 66 | 23 | 25 |
|  Patients with  improvement, n (%) | 47 (49.5) | 54 (59.3) | 34 (47.2) | 38 (57.6) | 13 (56.5) | 16 (64.0) |
| OR (90% CI) |  | 1.54 (0.94, 2.53) |  | 1.59 (0.90, 2.82) |  | 1.42 (0.53, 3.83) |
| pvalue |  | 0.152 |  | 0.180 |  | 0.559 |
| Swollen and tender joint counts |  |  |  |  |  |  |
|  n | 102 | 104 | 76 | 78 | 26 | 26 |
|  Mean change from  baseline (SD) | –3.4 (5.9) | –5.4 (6.8) | –3.0 (5.8) | –5.0 (6.3) | –4.5 (6.1) | –6.8 (8.0) |
| Difference vs. placebo (SE) |  | –1.9 (0.7) |  | –2.0 (0.8) |  | –1.4 (1.4) |
| pvalue |  | 0.005 |  | 0.009 |  | 0.306 |

aPatients with mCLASI activity score >0 at baseline who achieved ≥50% improvement from baseline.

BILAG, British Isles Lupus Assessment Group; IFNGS, interferon gene signature; mCLASI, modified Cutaneous Lupus Erythematosus Disease Area and Severity Index; Q4W, every 4 weeks; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.