

**Outcomes of patients with systemic lupus erythematosus treated with intravenous or
subcutaneous belimumab: a post-hoc efficacy meta-analysis by BICLA criteria**

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SUPPLEMENTAL MATERIAL

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Supplemental Table S1. BICLA response from week 4 through week 52 in patients with SLE treated with belimumab versus placebo in the pooled BLISS study population.

| | BEL; n (%); N | PBO; n (%); N | OR | 95% CI | <i>p</i> value |
|-----------------------|--------------------|--------------------|------|-----------|------------------|
| BICLA response | | | | | |
| BICLA at week 4 | 423 (25.0); N=1693 | 261 (23.6); N=1108 | 1.08 | 0.90–1.29 | 0.404 |
| BICLA at week 8 | 557 (32.9); N=1693 | 305 (27.5); N=1108 | 1.27 | 1.07–1.50 | 0.006 |
| BICLA at week 12 | 635 (37.6); N=1691 | 350 (31.6); N=1107 | 1.29 | 1.09–1.52 | 0.002 |
| BICLA at week 16 | 716 (42.3); N=1692 | 373 (33.6); N=1109 | 1.42 | 1.21–1.67 | <0.001 |
| BICLA at week 20 | 733 (43.3); N=1692 | 388 (35.0); N=1108 | 1.39 | 1.18–1.62 | <0.001 |
| BICLA at week 24 | 781 (46.2); N=1691 | 401 (36.2); N=1107 | 1.47 | 1.26–1.72 | <0.001 |
| BICLA at week 28 | 744 (44.0); N=1692 | 374 (33.8); N=1107 | 1.51 | 1.29–1.78 | <0.001 |
| BICLA at week 32 | 756 (44.7); N=1693 | 392 (35.4); N=1108 | 1.43 | 1.22–1.67 | <0.001 |
| BICLA at week 36 | 735 (43.4); N=1692 | 391 (35.3); N=1107 | 1.37 | 1.17–1.60 | <0.001 |
| BICLA at week 40 | 757 (44.8); N=1691 | 387 (34.9); N=1108 | 1.48 | 1.26–1.73 | <0.001 |
| BICLA at week 44 | 758 (44.8); N=1691 | 394 (35.5); N=1109 | 1.45 | 1.24–1.70 | <0.001 |
| BICLA at week 48 | 746 (44.1); N=1692 | 382 (34.4); N=1109 | 1.48 | 1.27–1.74 | <0.001 |
| BICLA at week 52 | 754 (44.6); N=1692 | 385 (34.7); N=1108 | 1.47 | 1.25–1.72 | <0.001 |

Results from logistic regression analysis adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo.

Supplemental Table S2. BICLA response from week 4 through week 52 in patients with SLEDAI-2K ≥ 10 at baseline treated with belimumab versus placebo.

| | BEL; n (%); N | PBO; n (%); N | OR | 95% CI | <i>p</i> value |
|-----------------------|--------------------|-------------------|------|-----------|------------------|
| BICLA response | | | | | |
| BICLA at week 4 | 254 (24.2); N=1051 | 131 (19.5); N=673 | 1.34 | 1.05–1.71 | 0.017 |
| BICLA at week 8 | 349 (33.2); N=1051 | 168 (25.0); N=673 | 1.45 | 1.17–1.81 | 0.001 |
| BICLA at week 12 | 399 (38.0); N=1051 | 196 (29.1); N=673 | 1.47 | 1.19–1.82 | <0.001 |
| BICLA at week 16 | 435 (41.4); N=1051 | 199 (29.5); N=674 | 1.66 | 1.35–2.05 | <0.001 |
| BICLA at week 20 | 452 (43.0); N=1051 | 218 (32.3); N=674 | 1.56 | 1.27–1.92 | <0.001 |
| BICLA at week 24 | 499 (47.5); N=1051 | 225 (33.4); N=673 | 1.76 | 1.43–2.15 | <0.001 |
| BICLA at week 28 | 462 (44.0); N=1051 | 204 (30.3); N=673 | 1.76 | 1.43–2.16 | <0.001 |
| BICLA at week 32 | 475 (45.2); N=1051 | 204 (30.3); N=674 | 1.82 | 1.48–2.24 | <0.001 |
| BICLA at week 36 | 455 (43.3); N=1051 | 206 (30.6); N=673 | 1.68 | 1.37–2.07 | <0.001 |
| BICLA at week 40 | 477 (45.4); N=1051 | 204 (30.3); N=673 | 1.86 | 1.52–2.29 | <0.001 |
| BICLA at week 44 | 477 (45.4); N=1051 | 206 (30.6); N=674 | 1.85 | 1.50–2.28 | <0.001 |
| BICLA at week 48 | 458 (43.6); N=1051 | 208 (30.9); N=674 | 1.71 | 1.39–2.10 | <0.001 |
| BICLA at week 52 | 457 (43.5); N=1051 | 208 (30.9); N=673 | 1.67 | 1.36–2.06 | <0.001 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo; SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000.

Supplemental Table S3. BICLA response from week 4 through week 52 in patients with SLEDAI-2K <10 at baseline treated with belimumab versus placebo.

| | BEL; n (%); N | PBO; n (%); N | OR | 95% CI | <i>p</i> value |
|-----------------------|---------------------|---------------------|------|-----------|----------------|
| BICLA response | | | | | |
| BICLA at week 4 | 169 (26.3); N = 642 | 130 (29.9); N = 435 | 0.81 | 0.62–1.07 | 0.144 |
| BICLA at week 8 | 208 (32.4); N = 642 | 137 (31.5); N = 435 | 1.01 | 0.77–1.31 | 0.961 |
| BICLA at week 12 | 236 (36.9); N = 640 | 154 (35.5); N = 434 | 1.05 | 0.81–1.36 | 0.715 |
| BICLA at week 16 | 281 (43.8); N = 641 | 174 (40.0); N = 435 | 1.12 | 0.87–1.44 | 0.367 |
| BICLA at week 20 | 281 (43.8); N = 641 | 170 (39.2); N = 434 | 1.15 | 0.89–1.48 | 0.282 |
| BICLA at week 24 | 282 (44.1); N = 640 | 176 (40.6); N = 434 | 1.12 | 0.87–1.44 | 0.389 |
| BICLA at week 28 | 282 (44.0); N = 641 | 170 (39.2); N = 434 | 1.21 | 0.94–1.56 | 0.141 |
| BICLA at week 32 | 281 (43.8); N = 642 | 188 (43.3); N = 434 | 1.00 | 0.78–1.29 | 0.993 |
| BICLA at week 36 | 280 (43.7); N = 641 | 185 (42.6); N = 434 | 1.01 | 0.79–1.30 | 0.942 |
| BICLA at week 40 | 280 (43.8); N = 640 | 183 (42.1); N = 435 | 1.05 | 0.81–1.34 | 0.723 |
| BICLA at week 44 | 281 (43.9); N = 640 | 188 (43.2); N = 435 | 1.00 | 0.78–1.29 | 0.973 |
| BICLA at week 48 | 288 (44.9); N = 641 | 174 (40.0); N = 435 | 1.20 | 0.93–1.54 | 0.162 |
| BICLA at week 52 | 297 (46.3); N = 641 | 177 (40.7); N = 435 | 1.20 | 0.94–1.55 | 0.146 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo; SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000.

Supplemental Table S4. BICLA response from week 4 through week 52 in patients with positive anti-dsDNA levels at baseline treated with belimumab versus placebo.

| | BEL; n (%); N | PBO; n (%); N | OR | 95% CI | <i>p</i> value |
|-----------------------|--------------------|-------------------|------|-----------|------------------|
| BICLA response | | | | | |
| BICLA at week 4 | 326 (27.1); N=1204 | 181 (23.8); N=762 | 1.19 | 0.96–1.47 | 0.107 |
| BICLA at week 8 | 420 (34.9); N=1204 | 217 (28.5); N=762 | 1.31 | 1.07–1.60 | 0.009 |
| BICLA at week 12 | 467 (38.9); N=1202 | 241 (31.6); N=762 | 1.38 | 1.14–1.67 | 0.001 |
| BICLA at week 16 | 528 (43.9); N=1203 | 255 (33.4); N=763 | 1.53 | 1.26–1.85 | <0.001 |
| BICLA at week 20 | 543 (45.1); N=1203 | 259 (33.9); N=763 | 1.57 | 1.30–1.90 | <0.001 |
| BICLA at week 24 | 581 (48.3); N=1202 | 273 (35.8); N=762 | 1.63 | 1.35–1.97 | <0.001 |
| BICLA at week 28 | 544 (45.2); N=1203 | 255 (33.5); N=762 | 1.63 | 1.35–1.97 | <0.001 |
| BICLA at week 32 | 557 (46.3); N=1204 | 266 (34.9); N=763 | 1.56 | 1.29–1.89 | <0.001 |
| BICLA at week 36 | 537 (44.6); N=1203 | 259 (34.0); N=762 | 1.53 | 1.26–1.85 | <0.001 |
| BICLA at week 40 | 557 (46.3); N=1202 | 251 (32.9); N=762 | 1.73 | 1.43–2.09 | <0.001 |
| BICLA at week 44 | 558 (46.4); N=1202 | 261 (34.2); N=763 | 1.63 | 1.35–1.97 | <0.001 |
| BICLA at week 48 | 543 (45.1); N=1203 | 252 (33.0); N=763 | 1.64 | 1.35–1.99 | <0.001 |
| BICLA at week 52 | 545 (45.3); N=1203 | 255 (33.5); N=762 | 1.59 | 1.31–1.92 | <0.001 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

Anti-dsDNA: anti double-stranded DNA antibodies; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo.

Supplemental Table S5. BICLA response from week 4 through week 52 in patients negative for anti-dsDNA at baseline treated with belimumab versus placebo.

| | BEL; n (%); N | PBO; n (%); N | OR | 95% CI | <i>p</i> value |
|-----------------------|-------------------|-------------------|------|-----------|----------------|
| BICLA response | | | | | |
| BICLA at week 4 | 97 (19.8); N=489 | 80 (23.1); N=346 | 0.82 | 0.58–1.15 | 0.245 |
| BICLA at week 8 | 137 (28.0); N=489 | 88 (25.4); N=346 | 1.15 | 0.83–1.58 | 0.401 |
| BICLA at week 12 | 168 (34.4); N=489 | 109 (31.6); N=346 | 1.08 | 0.80–1.45 | 0.634 |
| BICLA at week 16 | 188 (38.4); N=489 | 118 (34.1); N=346 | 1.17 | 0.87–1.57 | 0.306 |
| BICLA at week 20 | 190 (38.9); N=489 | 129 (37.4); N=346 | 1.01 | 0.76–1.36 | 0.937 |
| BICLA at week 24 | 200 (40.9); N=489 | 128 (37.1); N=346 | 1.13 | 0.85–1.51 | 0.400 |
| BICLA at week 28 | 200 (40.9); N=489 | 119 (34.5); N=346 | 1.26 | 0.94–1.69 | 0.124 |
| BICLA at week 32 | 199 (40.7); N=489 | 126 (36.5); N=346 | 1.13 | 0.85–1.51 | 0.399 |
| BICLA at week 36 | 198 (40.5); N=489 | 132 (38.3); N=346 | 1.05 | 0.79–1.40 | 0.731 |
| BICLA at week 40 | 200 (40.9); N=489 | 136 (39.3); N=346 | 1.02 | 0.76–1.35 | 0.913 |
| BICLA at week 44 | 200 (40.9); N=489 | 133 (38.4); N=346 | 1.10 | 0.82–1.46 | 0.524 |
| BICLA at week 48 | 203 (41.5); N=489 | 130 (37.6); N=346 | 1.18 | 0.88–1.57 | 0.269 |
| BICLA at week 52 | 209 (42.7); N=489 | 130 (37.6); N=346 | 1.22 | 0.92–1.63 | 0.172 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

Anti-dsDNA: anti double-stranded DNA antibodies; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo.

Supplemental Table S6. BICLA response from week 4 through week 52 in patients with positive anti-dsDNA levels and/or low C3 and/or C4 levels at baseline treated with belimumab versus placebo.

| | BEL; n (%) | PBO; n (%) | OR | 95% CI | <i>p</i> value |
|-----------------------|--------------------|-------------------|------|-----------|------------------|
| BICLA response | | | | | |
| BICLA at week 4 | 346 (25.9); N=1335 | 203 (23.5); N=865 | 1.13 | 0.93–1.39 | 0.223 |
| BICLA at week 8 | 460 (34.5); N=1335 | 244 (28.2); N=865 | 1.30 | 1.08–1.57 | 0.006 |
| BICLA at week 12 | 516 (38.7); N=1333 | 272 (31.4); N=865 | 1.38 | 1.15–1.66 | 0.001 |
| BICLA at week 16 | 580 (43.5); N=1334 | 292 (33.7); N=866 | 1.49 | 1.25–1.79 | <0.001 |
| BICLA at week 20 | 596 (44.7); N=1334 | 301 (34.8); N=866 | 1.49 | 1.25–1.78 | <0.001 |
| BICLA at week 24 | 638 (47.9); N=1333 | 311 (36.0); N=865 | 1.61 | 1.34–1.92 | <0.001 |
| BICLA at week 28 | 602 (45.1); N=1334 | 290 (33.5); N=865 | 1.62 | 1.35–1.94 | <0.001 |
| BICLA at week 32 | 612 (45.8); N=1335 | 302 (34.9); N=866 | 1.55 | 1.29–1.85 | <0.001 |
| BICLA at week 36 | 592 (44.4); N=1334 | 299 (34.6); N=865 | 1.48 | 1.24–1.77 | <0.001 |
| BICLA at week 40 | 609 (45.7); N=1333 | 293 (33.9); N=865 | 1.62 | 1.36–1.94 | <0.001 |
| BICLA at week 44 | 608 (45.6); N=1333 | 301 (34.8); N=866 | 1.55 | 1.30–1.86 | <0.001 |
| BICLA at week 48 | 597 (44.8); N=1334 | 292 (33.7); N=866 | 1.58 | 1.32–1.89 | <0.001 |
| BICLA at week 52 | 597 (44.8); N=1334 | 293 (33.9); N=865 | 1.54 | 1.29–1.85 | <0.001 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

Anti-dsDNA: anti double-stranded DNA antibodies; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; C3: complement component 3; C4: complement component 4; OR: odds ratio; PBO: placebo.

Supplemental Table S7. BICLA response from week 4 through week 52 in patients negative for anti-dsDNA and with normal/high C3 and C4 levels at baseline treated with belimumab versus placebo.

| | BEL; n (%) | PBO; n (%) | OR | 95% CI | <i>p</i> value |
|-----------------------|-------------------|------------------|------|-----------|----------------|
| BICLA response | | | | | |
| BICLA at week 4 | 77 (21.5); N=358 | 58 (23.9); N=243 | 0.89 | 0.60–1.32 | 0.558 |
| BICLA at week 8 | 97 (27.1); N=358 | 61 (25.1); N=243 | 1.11 | 0.76–1.63 | 0.581 |
| BICLA at week 12 | 119 (33.2); N=358 | 78 (32.2); N=242 | 0.97 | 0.68–1.39 | 0.873 |
| BICLA at week 16 | 136 (38.0); N=358 | 81 (33.3); N=243 | 1.13 | 0.80–1.61 | 0.483 |
| BICLA at week 20 | 137 (38.3); N=358 | 87 (36.0); N=242 | 1.02 | 0.72–1.45 | 0.900 |
| BICLA at week 24 | 143 (39.9); N=358 | 90 (37.2); N=242 | 1.03 | 0.73–1.46 | 0.857 |
| BICLA at week 28 | 142 (39.7); N=358 | 84 (34.7); N=242 | 1.16 | 0.82–1.65 | 0.392 |
| BICLA at week 32 | 144 (40.2); N=358 | 90 (37.2); N=242 | 1.03 | 0.73–1.46 | 0.855 |
| BICLA at week 36 | 143 (39.9); N=358 | 92 (38.0); N=242 | 0.99 | 0.70–1.40 | 0.974 |
| BICLA at week 40 | 148 (41.3); N=358 | 94 (38.7); N=243 | 1.02 | 0.72–1.44 | 0.912 |
| BICLA at week 44 | 150 (41.9); N=358 | 93 (38.3); N=243 | 1.12 | 0.79–1.57 | 0.521 |
| BICLA at week 48 | 149 (41.6); N=358 | 90 (37.0); N=243 | 1.17 | 0.83–1.65 | 0.377 |
| BICLA at week 52 | 157 (43.9); N=358 | 92 (37.9); N=243 | 1.22 | 0.87–1.72 | 0.253 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

Anti-dsDNA: anti double-stranded DNA antibodies; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; C3: complement component 3; C4: complement component; OR: odds ratio; PBO: placebo.

Supplemental Table S8. BICLA response from week 4 through week 52 in patients with a prednisone equivalent dose >7.5 mg/day at baseline treated with belimumab versus placebo.

| | BEL; n (%) | PBO; n (%) | OR | 95% CI | <i>p</i> value |
|-----------------------|--------------------|-------------------|------|-----------|------------------|
| BICLA response | | | | | |
| BICLA at week 4 | 283 (26.6); N=1064 | 160 (23.5); N=680 | 1.22 | 0.97–1.53 | 0.089 |
| BICLA at week 8 | 365 (34.3); N=1064 | 203 (29.9); N=680 | 1.21 | 0.99–1.49 | 0.076 |
| BICLA at week 12 | 408 (38.4); N=1063 | 223 (32.8); N=680 | 1.30 | 1.06–1.59 | 0.013 |
| BICLA at week 16 | 458 (43.0); N=1064 | 231 (33.9); N=681 | 1.46 | 1.19–1.79 | <0.001 |
| BICLA at week 20 | 475 (44.7); N=1063 | 239 (35.1); N=681 | 1.48 | 1.21–1.80 | <0.001 |
| BICLA at week 24 | 499 (46.9); N=1063 | 253 (37.2); N=680 | 1.47 | 1.20–1.79 | <0.001 |
| BICLA at week 28 | 484 (45.5); N=1063 | 237 (34.9); N=680 | 1.52 | 1.25–1.86 | <0.001 |
| BICLA at week 32 | 481 (45.2); N=1064 | 246 (36.1); N=681 | 1.41 | 1.15–1.72 | 0.001 |
| BICLA at week 36 | 465 (43.7); N=1063 | 251 (36.9); N=680 | 1.29 | 1.05–1.57 | 0.014 |
| BICLA at week 40 | 483 (45.4); N=1063 | 245 (36.0); N=680 | 1.45 | 1.19–1.77 | <0.001 |
| BICLA at week 44 | 488 (45.9); N=1063 | 258 (37.9); N=681 | 1.37 | 1.12–1.67 | 0.002 |
| BICLA at week 48 | 477 (44.8); N=1064 | 246 (36.1); N=681 | 1.42 | 1.16–1.73 | 0.001 |
| BICLA at week 52 | 481 (45.2); N=1064 | 249 (36.6); N=680 | 1.39 | 1.14–1.70 | 0.001 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo.

Supplemental Table S9. BICLA response from week 4 through week 52 in patients with a prednisone equivalent dose ≤ 7.5 mg/day at baseline treated with belimumab versus placebo.

| | BEL; n (%) | PBO; n (%) | OR | 95% CI | <i>p</i> value |
|-----------------------|-------------------|-------------------|------|-----------|------------------|
| BICLA response | | | | | |
| BICLA at week 4 | 140 (22.3); N=629 | 101 (23.6); N=428 | 0.87 | 0.64–1.17 | 0.343 |
| BICLA at week 8 | 192 (30.5); N=629 | 102 (23.8); N=427 | 1.38 | 1.04–1.83 | 0.027 |
| BICLA at week 12 | 227 (36.1); N=628 | 127 (29.7); N=428 | 1.27 | 0.97–1.66 | 0.083 |
| BICLA at week 16 | 258 (41.1); N=628 | 142 (33.2); N=427 | 1.36 | 1.04–1.76 | 0.022 |
| BICLA at week 20 | 258 (41.0); N=629 | 149 (34.9); N=427 | 1.25 | 1.96–1.62 | 0.098 |
| BICLA at week 24 | 282 (44.9); N=628 | 148 (34.7); N=427 | 1.48 | 1.14–1.92 | 0.003 |
| BICLA at week 28 | 260 (41.3); N=629 | 137 (32.1); N=427 | 1.52 | 1.16–1.97 | 0.002 |
| BICLA at week 32 | 275 (43.7); N=629 | 146 (34.2); N=427 | 1.48 | 1.14–1.92 | 0.003 |
| BICLA at week 36 | 270 (42.9); N=629 | 140 (32.8); N=427 | 1.53 | 1.18–1.99 | 0.001 |
| BICLA at week 40 | 274 (43.6); N=628 | 142 (33.2); N=428 | 1.53 | 1.18–1.99 | 0.001 |
| BICLA at week 44 | 270 (43.0); N=628 | 136 (31.8); N=428 | 1.62 | 1.25–2.11 | <0.001 |
| BICLA at week 48 | 269 (42.8); N=628 | 136 (31.8); N=428 | 1.62 | 1.25–2.11 | <0.001 |
| BICLA at week 52 | 273 (43.5); N=628 | 136 (31.8); N=428 | 1.64 | 1.26–2.13 | <0.001 |

Results from logistic regression analysis, adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference. Data are presented as the number of events (percentage), odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo.

Supplemental Table S10. Influence of concomitant antimalarial treatment on BICLA response at week 52.

| | Group 1 | Group 2 | OR | 95% CI | <i>p</i> value |
|-----------------------|--------------------|-------------------|------|-----------|------------------|
| BICLA response | | | | | |
| | BEL; n (%) | PBO; n (%) | | | |
| BICLA at week 52 | 213 (41.3); N=774 | 105 (31.3); N=335 | 1.25 | 0.95–1.64 | 0.0114 |
| | PBO + AMA; n (%) | PBO; n (%) | | | |
| BICLA at week 52 | 280 (36.2); N=774 | 105 (31.3); N=335 | 1.51 | 1.13–2.02 | 0.005 |
| | BEL + AMA; n (%) | PBO; n (%) | | | |
| BICLA at week 52 | 541 (46.0); N=1177 | 105 (31.3); N=335 | 1.82 | 1.40–2.37 | <0.001 |
| | BEL + AMA; n (%) | BEL; n (%) | | | |
| BICLA at week 52 | 541 (46.0); N=1177 | 213 (41.3); N=774 | 1.22 | 0.99–1.51 | 0.065 |

Results from univariable logistic regression analysis of BICLA response at week 52 in subgroups of patients stratified based on treatment arm and concomitant treatment with antimalarial agents. Data are presented as numbers, odds ratio (OR), 95% confidence interval (CI), and *p* value for each comparison. Statistically significant *p* values are in bold.

AMA: antimalarial agents; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; OR: odds ratio; PBO: placebo.

Supplemental Table S11. Factors associated with BICLA response at week 52 in patients with SLE in the pooled belimumab trial population.

| | N | OR | 95% CI | <i>p</i> value |
|---|------|------|-----------|------------------|
| Demographics | | | | |
| Age | 2802 | 1.00 | 0.99–1.00 | 0.501 |
| Male sex | 2802 | 1.04 | 0.75–1.44 | 0.806 |
| Race (ref.: White/Caucasian) | 2802 | | | |
| Asian | | 1.17 | 0.92–1.49 | 0.206 |
| Black/African American | | 0.76 | 0.54–1.08 | 0.127 |
| Indigenous American | | 1.34 | 1.02–1.76 | 0.036 |
| Clinical Features | | | | |
| BMI at baseline | 2707 | 0.99 | 0.98–1.00 | 0.131 |
| SLE disease duration at baseline | 2801 | 0.98 | 0.97–0.99 | 0.001 |
| cSLEDAI-2K score at baseline | 2802 | 0.78 | 0.66–0.91 | 0.001 |
| SDI score ≥ 1 at baseline | 2802 | 0.74 | 0.63–0.87 | <0.001 |
| SDI score ≥ 2 at baseline | 2802 | 0.63 | 0.50–0.79 | <0.001 |
| Serological status | | | | |
| Anti-dsDNA (+) at baseline | 2802 | 0.98 | 0.83–1.15 | 0.770 |
| Anti-Smith (+) | | | | |
| at baseline | 1808 | 0.78 | 0.63–0.95 | 0.016 |
| at any measurement during follow-up | 1810 | 0.77 | 0.62–0.94 | 0.012 |
| Anti-RNP (+) | | | | |
| at baseline | 1204 | 0.68 | 0.53–0.87 | 0.002 |
| at any measurement during follow-up | 1207 | 0.67 | 0.52–0.87 | 0.002 |
| Anti-ribosomal P (+) | | | | |
| at baseline | 2203 | 0.88 | 0.73–1.06 | 0.192 |
| at any measurement during follow-up | 2203 | 0.89 | 0.74–1.07 | 0.211 |
| aPL (+) at baseline | | | | |
| aCL | | | | |
| IgA | 2676 | 1.04 | 0.62–1.74 | 0.892 |
| IgG | 2680 | 0.75 | 0.59–0.95 | 0.019 |
| IgM | 2680 | 0.82 | 0.63–1.06 | 0.136 |
| Anti- $\beta 2$ GPI | | | | |
| IgA | 1212 | 0.92 | 0.68–1.24 | 0.593 |
| IgG | 1212 | 1.40 | 0.69–2.82 | 0.354 |
| IgM | 1212 | 0.87 | 0.53–1.42 | 0.567 |
| LAC | 1197 | 1.13 | 0.83–1.53 | 0.432 |
| aPL (+) at any measurement during follow-up | 2684 | 0.89 | 0.75–1.06 | 0.190 |
| BLyS/BAFF levels at baseline | 2348 | 0.90 | 0.84–0.96 | 0.001 |

| | | | | |
|---------------------------------------|------|------|-----------|------------------|
| Low C3 at baseline | 2802 | 0.80 | 0.68–0.94 | 0.006 |
| Low C4 at baseline | 2802 | 0.75 | 0.64–0.89 | 0.001 |
| Medications | | | | |
| Pred eq. dose >7.5 mg/day at baseline | 2802 | 1.10 | 0.94–1.29 | 0.232 |
| AMA at baseline | 2802 | 1.21 | 1.03–1.43 | 0.024 |
| Immunosuppressants at baseline | 2802 | | | |
| Azathioprine | | 0.89 | 0.73–1.08 | 0.247 |
| Methotrexate | | 0.91 | 0.72–1.15 | 0.441 |
| Mycophenolic acid | | 0.86 | 0.69–1.06 | 0.152 |
| Cyclophosphamide | | 0.98 | 0.52–1.87 | 0.963 |
| Tacrolimus | | 0.68 | 0.43–1.08 | 0.102 |
| Ciclosporin | | 0.89 | 0.54–1.48 | 0.657 |
| Leflunomide | | 0.73 | 0.44–1.20 | 0.211 |
| BEL approved dose | 2802 | 1.47 | 1.25–1.72 | <0.001 |

Results from logistic regression analysis adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference, with BICLA response at week 52 as the dependant variable. Data are presented as numbers, odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold.

(+): positive; aCL: anti-cardiolipin antibodies; AMA: antimalarial agents; anti-dsDNA: anti-double-stranded DNA antibodies; anti-RNP: anti-U1-ribonucleoprotein antibodies; anti- β 2GPI: anti- β 2 glycoprotein I antibodies; aPL: antiphospholipid antibodies; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; BLyS/BAFF: B-Lymphocyte stimulator/ B cell activating factor belonging to the tumour necrosis factor family; BMI: body mass index; CI: confidence interval; cSLEDAI-2K: clinical Systemic Lupus Erythematosus Disease Activity Index 2000; C3: complement component 3; C4: complement component 4; eq.: equivalent; Ig: immunoglobulin; LAC: lupus anticoagulant; OR: odds ratio; Pred.: prednisone; SDI: Systemic Lupus International Collaborating Clinics (SLICC)/American College of Rheumatology (ACR) Damage Index; SLE: systemic lupus erythematosus.

Supplemental Table S12. Factors associated with BICLA response at week 52 in patients with SLE in the pooled belimumab trial population by multivariable analysis.

| | OR | 95% CI | <i>p</i> value |
|----------------------------------|------|-----------|------------------|
| Demographics | | | |
| Age | 1.00 | 0.99–1.01 | 0.868 |
| Male sex | 1.08 | 0.77–1.51 | 0.664 |
| Race (ref.: White/Caucasian) | | | |
| Asian | 1.18 | 0.91–1.51 | 0.209 |
| Black/African American | 0.79 | 0.56–1.13 | 0.196 |
| Indigenous American | 1.30 | 0.98–1.73 | 0.064 |
| Clinical Features | | | |
| SLE disease duration at baseline | 0.99 | 0.97–1.00 | 0.077 |
| cSLEDAI-2K score at baseline | 0.83 | 0.70–0.98 | 0.030 |
| SDI >2 score at baseline | 0.68 | 0.53–0.88 | 0.003 |
| Serological status | | | |
| aCL IgG (+) at baseline | 0.84 | 0.65–1.08 | 0.163 |
| Low C3 at baseline | 0.90 | 0.74–1.09 | 0.265 |
| Low C4 at baseline | 0.80 | 0.65–0.97 | 0.025 |
| Medications | | | |
| AMA at baseline | 1.15 | 0.97–1.38 | 0.112 |
| BEL approved dose | 1.45 | 1.23–1.71 | <0.001 |

Results from multivariable logistic regression analysis adjusting for trial variance with BLISS-52 and BLISS-76 pooled as a reference, with BICLA response at week 52 as the dependant variable. Data are presented as the odds ratio (OR), 95% confidence interval (CI), and *p* value. Statistically significant *p* values are in bold. The total number of patients for this analysis was 2680.

(+): positive; aCL: anticardiolipin antibodies; AMA: antimalarials; BEL: belimumab; BICLA: British Isles Lupus Assessment Group (BILAG)-Based Composite Lupus Assessment; CI: confidence interval; cSLEDAI-2K: clinical Systemic Lupus Erythematosus Disease Activity Index 2000; C3: complement component 3; C4: complement component 4; eq.: equivalent; IgG: immunoglobulin G; OR: odds ratio; Pred.: prednisone; SDI: Systemic Lupus International Collaborating Clinics (SLICC)/American College of Rheumatology (ACR) Damage Index; SLE: systemic lupus erythematosus.