Supplementary Material

Methods – patients

Patients were ineligible for inclusion if they had received treatment with cyclophosphamide, mycophenolate mofetil/mycophenolic acid or leflunomide within 6 months of randomisation or cyclosporine (systemic), azathioprine, sulfasalazine, tacrolimus, tofacitinib, mizoribine, actarit, or bucillamine within 4 weeks of randomisation.

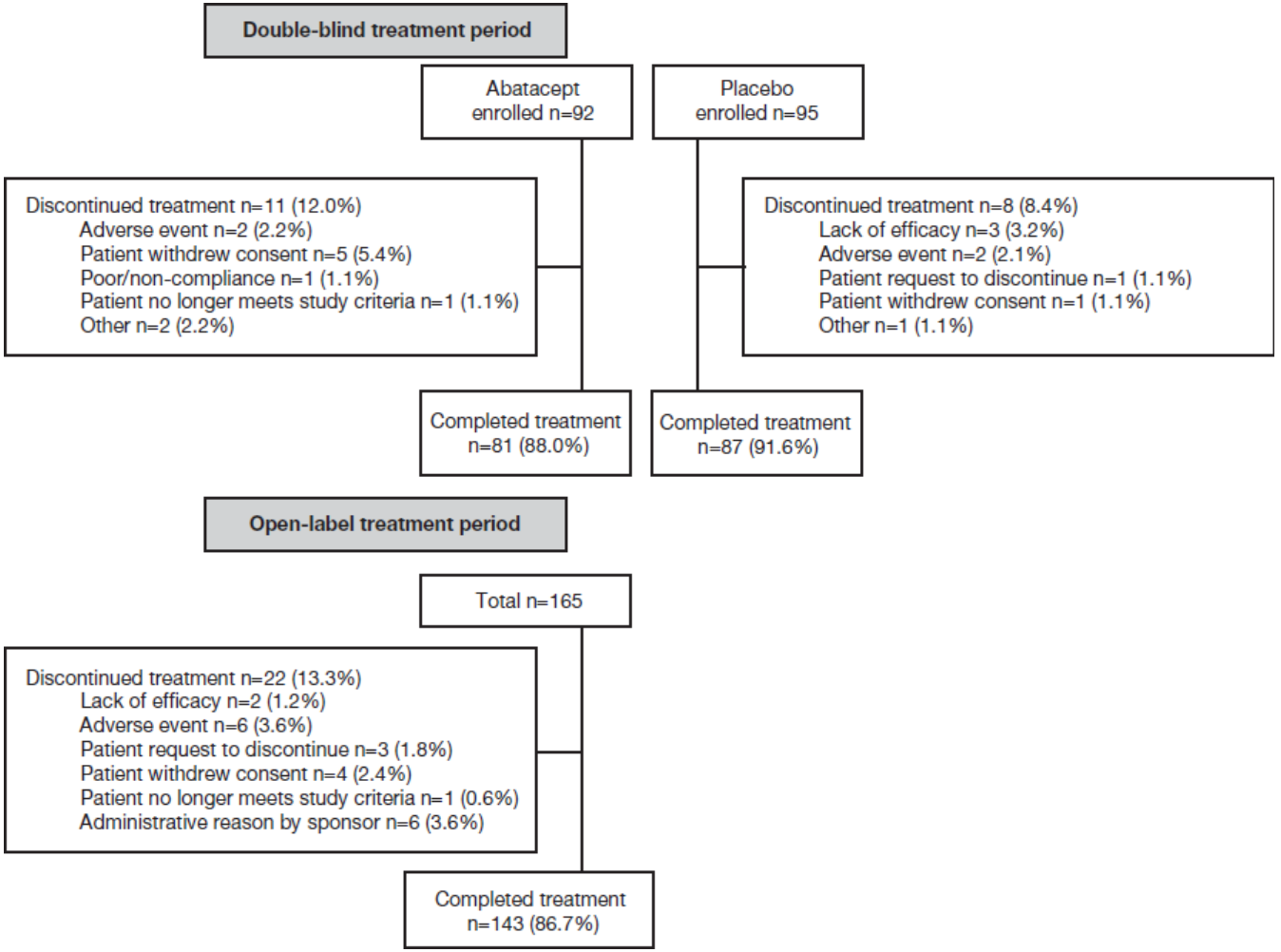
Methods – statistical analysis

A sample size of 172 patients (86 per arm) was needed to achieve 98% power to detect a treatment difference of 3 in changes from baseline in European League Against Rheumatism (EULAR) Sjögren's Syndrome Disease Activity Index (ESSDAI) score at Day 169 between the abatacept and placebo groups, using a two-sided *t*-test with a significance level of 0.05 and assuming a common standard deviation (SD) of 4.8. A sample size of 172 patients was needed to achieve 90% power to detect a treatment difference of 1 in change from baseline in EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) score at Day 169 when assuming a common SD of 2, and 91% power to detect a treatment difference in mean change from baseline of 0.165 mL/min in salivary flow when assuming a common SD of 0.275. Taking into account the hierarchical testing procedure, the overall power for the primary and the 2 key secondary endpoints was at least 80%.

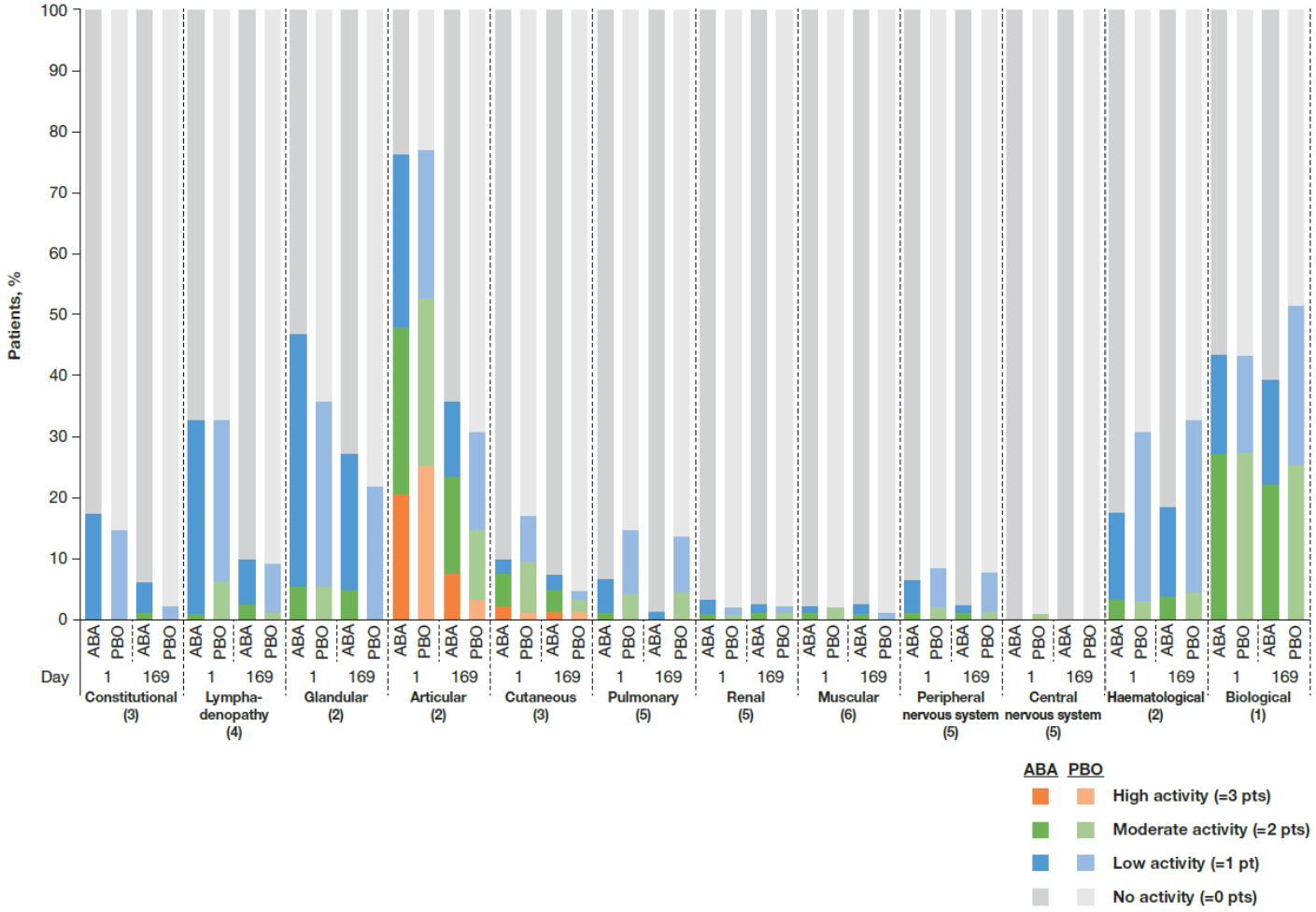
The primary and key secondary endpoints, and selected biomarkers, were analysed by a longitudinal repeated measures model, which included randomisation stratification factors current corticosteroid use (yes/no), current hydroxychloroquine use (yes/no), enrolment in Japan (yes/no) and stimulated whole salivary flow (SWSF) </≥0.1 mL/min. For the post hoc biomarker analyses, the Benjamini–Hochberg procedure was applied to control the false discovery rate at an alpha level of 5%.

Baer AN, *et al. Ann Rheum Dis* 2021; 80:339–348. doi: 10.1136/annrheumdis-2020-218599

Supplementary Figure S1 Patient disposition in double-blind and open-label treatment periods



Supplementary Figure S2 ESSDAI domains at baseline and Day 169



Maximum domain weights are indicated parenthetically on the x axis. ABA, abatacept; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; PBO, placebo; pt, points.