Meaningful Improvement in General Health Outcomes With Guselkumab

Treatment for Psoriatic Arthritis: Patient-Reported Outcomes Measurement

Information System-29 Results From a Phase 3 Study

For submission to: The Patient

Ana-Maria Orbai, Laura C. Coates, Atul Deodhar, Philip S. Helliwell, Christopher T.

Ritchlin,<sup>5</sup> Evan Leibowitz,<sup>6</sup> Alexa P. Kollmeier,<sup>7</sup> Elizabeth C. Hsia,<sup>7,8</sup> Xie L. Xu,<sup>7</sup> Shihong

Sheng, <sup>7</sup> Yusang Jiang, <sup>7,9</sup> Yan Liu, <sup>7</sup> Chenglong Han <sup>7</sup>

<sup>1</sup>Psoriatic Arthritis Program, Johns Hopkins University School of Medicine, Baltimore,

MD, USA; <sup>2</sup>Nuffield Department of Orthopaedics, University of Oxford, Oxford, UK;

<sup>3</sup>Division of Arthritis and Rheumatic Diseases, Oregon Health & Science University,

Portland, OR, USA; <sup>4</sup>Leeds Institute of Rheumatic and Musculoskeletal Medicine,

University of Leeds, Leeds, UK; <sup>5</sup>Department of Medicine, Allergy/Immunology and

Rheumatology, University of Rochester Medical Center, Rochester, NY, USA; <sup>6</sup>Janssen

Scientific Affairs, LLC, Horsham, PA, USA; <sup>7</sup>Janssen Research & Development, Spring

House, PA/San Diego CA, USA; 8University of Pennsylvania School of Medicine,

Philadelphia, PA, USA; <sup>9</sup>Cytel, Inc., Chesterbrook, PA, USA

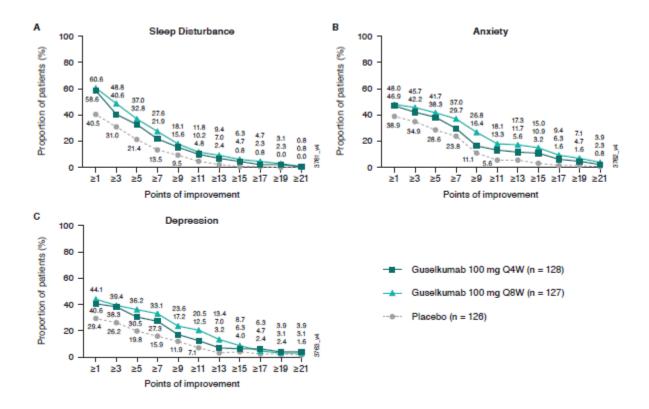
**Corresponding author:** 

Ana-Maria Orbai, MD MHS

Email: aorbai1@jhmi.edu

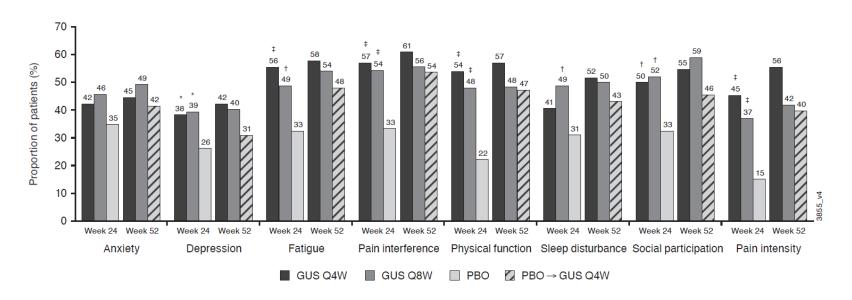
## SUPPLEMENTARY MATERIAL

Supplementary Fig 1. Cumulative distribution of points of improvement in PROMIS-29 sleep disturbance (A), anxiety (B), and depression (C) domain T-scores from baseline to Week 24.



PROMIS, Patient-Reported Outcomes Measurement Information System; Q4W, every 4 weeks; Q8W, every 8 weeks.

Supplementary Fig 2. Proportions of patients achieving ≥3-point improvements in PROMIS-29 domain T-scores from baseline to Week 24 and Week 52 (non-responder imputation).



Week 24: All patients, including those with imputed data (patients meeting treatment failure prior to Week 24 or with missing data at Week 24 were considered as not achieving ≥5-point improvement); P-values calculated using Cochran-Mantel-Haenszel test; nominal p-values vs PBO: \*p<0.05; †p<0.01; ‡p<0.001. GUS Q4W, n=128; GUS Q8W, n=127; PBO, n=126.

Week 52: Evaluable patients; after discontinuation of study agent for any reason, patients with missing data were considered non-responders.

GUS, guselkumab; PBO, placebo; PROMIS, Patient-Reported Outcomes Measurement Information System; Q4W, every 4 weeks; Q8W, every 8 weeks.