Supplemental Online Content

Bechara FG, Podda M, Prens EP, et al. Efficacy and safety of adalimumab in conjunction with surgery in moderate to severe hidradenitis suppurativa: the SHARPS randomized clinical Trial. *JAMA Surg*. Published online August 18, 2021. doi:10.1001/jamasurg.2021.3655

This supplemental material has been provided by the authors to give readers additional information about their work.

eMethods

Randomization and masking

The study findings were reported adhering to the CONsolidated Standards of Reporting Trials (CONSORT) checklist and guidelines.

All patients were assigned a unique identification number by interactive response technology during screening. On day 1 of the study, patients were randomized centrally and stratified by Hurley stage (II vs III) and anatomical location of the planned hidradenitis suppurativa (HS) surgical site (ie, axilla versus inguinal region) in a 1:1 ratio to adalimumab or placebo. AbbVie personnel, the study site personnel, investigator, surgeon, and the patient were blinded to the patient's treatment throughout the study.

Adalimumab and placebo were provided in a 1 mL pre-filled syringe containing adalimumab 40 mg/0.8 mL or matching placebo injection solution and was packaged in two pre-filled syringes per carton. Each adalimumab/placebo kit carton and syringe was labeled and had a unique kit ID.

Sample size

The study was designed to enroll approximately 200 patients. Based on the combined response rates for the hidradenitis suppurativa clinical response (HiSCR) at week 12 (50.6% for adalimumab vs 26.8% for placebo) from the PIONEER I and II studies in a general moderate-to-severe HS patient population[1] and considering potential differences versus the present study population of moderate to severe HS patients who are candidates for surgery, a conservative estimate of 20% treatment difference was used for the power calculation. Assuming at least a 20% treatment difference in this study population, 100 patients per treatment arm would provide at least 80% power to detect a treatment difference at the alpha level of 0.05 and to demonstrate the point estimate of the treatment difference of at least 15%.

Reference

1. Kimball AB, Okun MM, Williams DA, et al. Two phase 3 trials of adalimumab for hidradenitis suppurativa. *N Engl J Med.* 2016;375(5):422-434.

eTable. List of Investigators and Corresponding Independent Ethics Committee/Institutional Review Board

Principal Investigator	Site Name	Location	IEC/IEB
Afsaneh Alavi	York Dermatology Clinic and Research Centre	Richmond Hill, Ontario, Canada	Dup_Chesapeake IRB Services
Petr Arenberger	Fakultni nemocnice Kralovske Vinohrady	Praha, Czechia	Eticka komise Fakultni Nemocnice Kralovske Vinohrady
Maria Arredondo	Hospital Pablo Tobón Uribe	Medellin, Colombia	Hospital Pablo Tobon Uribe
Julio Bassas-Vilas	Hospital Universitari Germans Trias i Pujol	Barcelona, Spain	CEIC Hospital Universitari Germans Trias i Pujol
Falk Bechara	Klinikum fuer Dermatoologie Venerologie und Allergologie der Ruhr-Universtaet Bochum	Bochum, Germany	Ethik-Kommission der Medizinischen Fakultaet der Ruhr-Universität Bochum
Pierre Becherel	Hopital Prive d'Antony Service de Dermatologie	Anthony, France	Comite de protection des Personnes (CPP) IDF IV-Hosp Saint Louis
Vincenzo Bettoli	Azienda Ospedaliero-Universitaria A.O.U Sant'Anna di Ferrara, Dipartimento di Medicina Clinica e Specialistica-Sezione de Dermatologia	Ferrera, Italy	Comitato Etico AOU Policlinico S. Orsola-malpighi
Anthony Bewley	Barts Health NHS Trust - Whipps Cross University Hospital Department of Dermatology	London, UK	London - London Bridge Research Ethics Committee
Luca Bianchi	Policlinico Tor Vergata	Rome, Italy	Comitato Etico Indipendente Policlinico Tor Vergata
Erin Boh	Tulane University Health Science Center	New Orleans, LA	Tulane University Human Research Protection Office
Emel Bulbul Baskan	Uludag University Medical Faculty Uludag University of Medicine, Department of Dermatological and Venereal Diseases	Bursa, Turkey	Uludag Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu Gorukle

Principal Investigator	Site Name	Location	IEC/IEB
Vasiliki Chasapi	Andreas Syggros Hospital, 1st Department of Dermatology and Venereology, University of Athens	Athens, Greece	National Ethics Committee
Cristina Ciudad Blanco	Hospital Gregorio Maranon Servicio de Dermatologia Bloque B	Madrid, Spain	CEIC Hospital Universitari Germans Trias i Pujol
Veronique del Marmol	Hôpital Erasme -Service de Dermatologie	Bruxelles, Belgium	Comite d'Ethique de l'Hospital Erasme
Rieke Driessen	Radboud University Medical Center Dept. of Dermatology	Nijmegen, Netherlands	Medisch Ethische Toetsingscommissie Erasmus MC
Vicente Exposito Serrano	Corporacio Sanitaria Parc Tauli Servicio de Dermatologia	Sabadell, Spain	CEIC Hospital Universitari Germans Trias i Pujol
Evangelos J. Giamarellos-Bourboulis	Attikon University General Hospital, 4th Department of Internal Medicine	Athens, Greece	National Ethics Committee (Central) EC University General Hospital Attiko (Local)
Calin Giurcaneanu	Spitalul Universitar de Urgenta Elias Clinica de Dermatologie si Alergologie	Bucuresti, Romania	Comisia Nationala de Bioetica a Medicamentului si a Dispozitivelor Medicale
Minerva Gomez Florez	Hospital Universitario "Dr. José Eleuterio González"	Monterrey, Mexico	Comite de Etica en Investigacion del Hospital Universitario Doctor Jose Eleuterio Gonzalez
Sergey Goryunov	Moscow "City Clinical Hospital Number 15 named after O.M. Filatov"	Moscow, Russia	Moscow City Clinical Hospital Number 15
Barbara Horvath	Universitair Medisch Centrum Groningen Department of Dermatology	Groningen, Netherlands	RvB UMCG
Gregor B.E. Jemec	Sjaellands Universitets Hospital Roskilde Department of Dermatology	Roskilde, Denmark	Den Videnskabsetiske komite for region Sjaelland

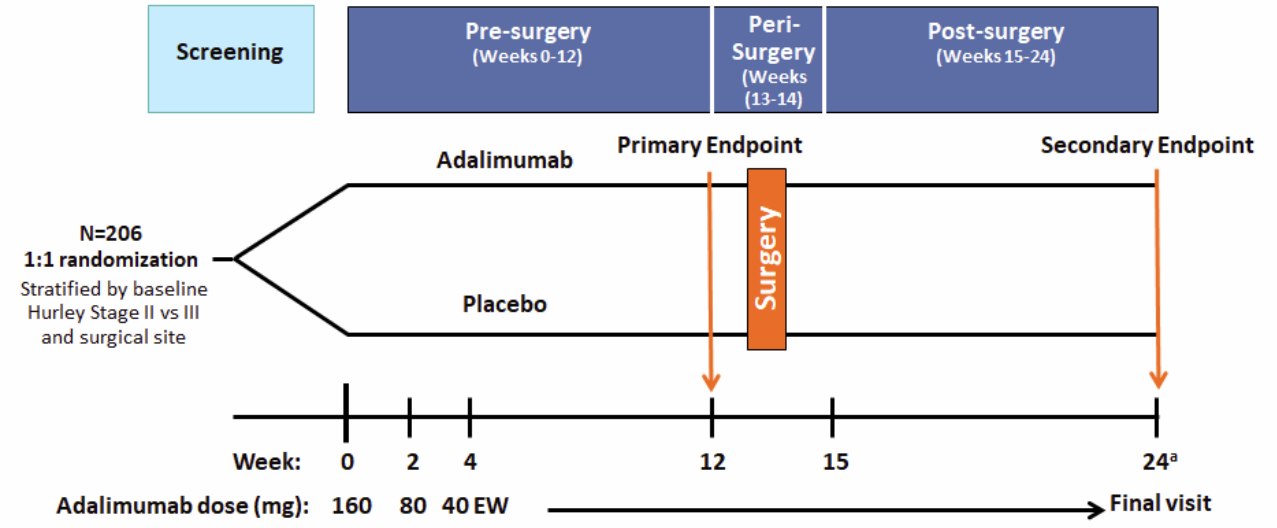
Principal Investigator	Site Name	Location	IEC/IEB
Alexandra B. Kimball	Beth Israel Deaconess Medical Center	Boston, MA, USA	Beth Israel Deaconess Committee Clinical Investigation (IRB)
Joslyn S. Kirby	Pennsylvania State University & Milton S. Hershey Med Center	Hershey, PA, USA	Quorum Institutional Review Board (IRB)
Georgios Kokolakis	Charité Universitätsmedizin Campus Mitte	Berlin, Germany	Ethik-Kommission der Medizinischen Fakultaet der Ruhr-Universität Bochum (Central) Ethik-Kommission des Landes Berlin (Local)
Carmen Lisbos	Centro Hospitalar de Sao Joao, EPE	Porto, Portugal	CEIC - Comissão de Ética para a Investigação Clínica
Aida Lugo-Somolinos	University of North Carolina at Chapel Hill	Chapel Hill, NC, USA	Quorum Institutional Review Board
Antonio Martorell Calatayud	Hospital de Manises Servicio de Dermatologia	Valencia, Spain	CEIC Hospital Universitari Germans Trias i Pujol
Natasha Mesinkovska	University of California Irvine	Irvine, CA, USA	Office of Research
Maurizio Podda	Klinikum Darmstadt GmbH Hautklinik Darmstadt-Eberstadt	Darmstadt, Germany	Ethik-Kommission der Medizinischen Fakultaet der Ruhr-Universität Bochum (Central) Ethik-Kommission der Landesarztekammer in Hessen (Local)
Errol Prens	Erasmus Medisch Centrum Department of Dermatology	Rotterdam, Netherlands	METC Erasmus MC
Abrar Qureshi	Rhode Island Hospital Dermatology Department	Providence, RI, USA	The Committee of the Protection of Human Subjects
Tooraj Raoof	Encino Research Center/T. Joseph Raoof, MD, Inc	Encino, CA, USA	Quorum Institutional Review Board
Konstantin Raznatovsky	Academy of Post Graduate Education named after I.I. Mechniko under the Ministry of	Saint Petersburg, Russia	Ethics Council under the Ministry of Healthcare of the Russian Federation (Central) University n.a. I.I. Mechnikov under the Ministry of Public

Principal Investigator	Site Name	Location	IEC/IEB
	Public Health of the Russian Federation Scientific Research Institution of mycology named after P. N.Kashkin		Health of the Russian Federation (Local)
Ziad Reguiai	Polyclinique Courlancy ment de dermatologie	Reims, France	Comite de protection des (CPP) IDF IV-Hosp Saint Louis
Dimitrios Rigopoulos	Andreas Syggros Hospital, 1st Department of Dermatology and Venereology, University of Athens	Athens, Greece	National Ethics Committee (Central) EC Skin & Venereal Hospital of Athens “Adreas Syggros”
Caius Solovan	Spitalul Municipal de Urgenta Timisoara	Timisoara, Romania	Comisia Nationala de Bioetica a Medicamentului si a Dispozitivelor Medicale
Michael Sticherling	Universitätsklinikum Erlangen	Erlangen, Germany	Ethik-Kommission der Medizinischen Fakultaet der Ruhr-Universität Bochum (Central) Ethik-Kommission der Medizinischen Fakultaet der Friedrich-Alexander-Universtaet Erlangen-Nuernberg (Local)
Jacek Szepietowski	Prywatny Osrodek Chirurgii Plastycznej Andrzej Bieniek	Wroclaw, Poland	Komisja Bioetyczna przy Dolnoslaskiej Izbie Lekarskiej
Simon Thomsen	Bispebjerg Hospital Department of Dermatology	Copenhagen, Denmark	Den Videnskabsetiske Komite For Region Sjaelland
Turid Thune	Haukeland University Hospital	Bergen, Norway	REK V Universitetet i Bergen
Yvetta Vantuchova	Fakultni Nemocnice Ostrava Kozni oddelen	Ostrava, Czechia	Fakultni Nemocnice Ostrava
Stefano Veraldi	Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico	Milan, Italy	Comitato Etico Milano Area B
Eva Vilarrasa Rull	Hospital Santa Creu i Sant Pau Servicio de Dermatologia	Barcelona, Spain	CEIC Hospital Universitari Germans Trias i Pujol

Principal Investigator	Site Name	Location	IEC/IEB
Christos C. Zouboulis	Städtisches Klinikum Dessau, Klinik für Dermatologie, Venerologie und Allergologie, Immunologisches Zentrum, Medizinische Hochschule Brandenburg Theodor Fontane	Dessau, Germany	Ethik-Kommission der Medizinischen Fakultaet der Ruhr-Universität Bochum (Central) Ethik-Kommission des Landes Sachsen-Anhalt (Local)

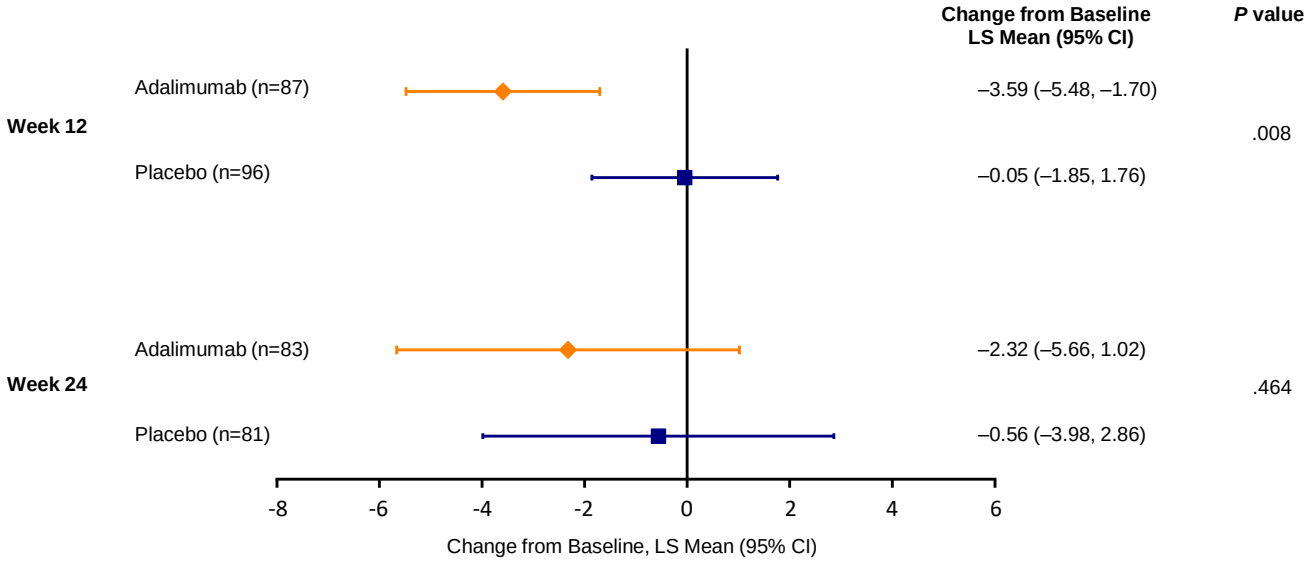
IEC, Independent Ethics Committee; IRB, Institutional Review Board.

eFigure 1. Study Design



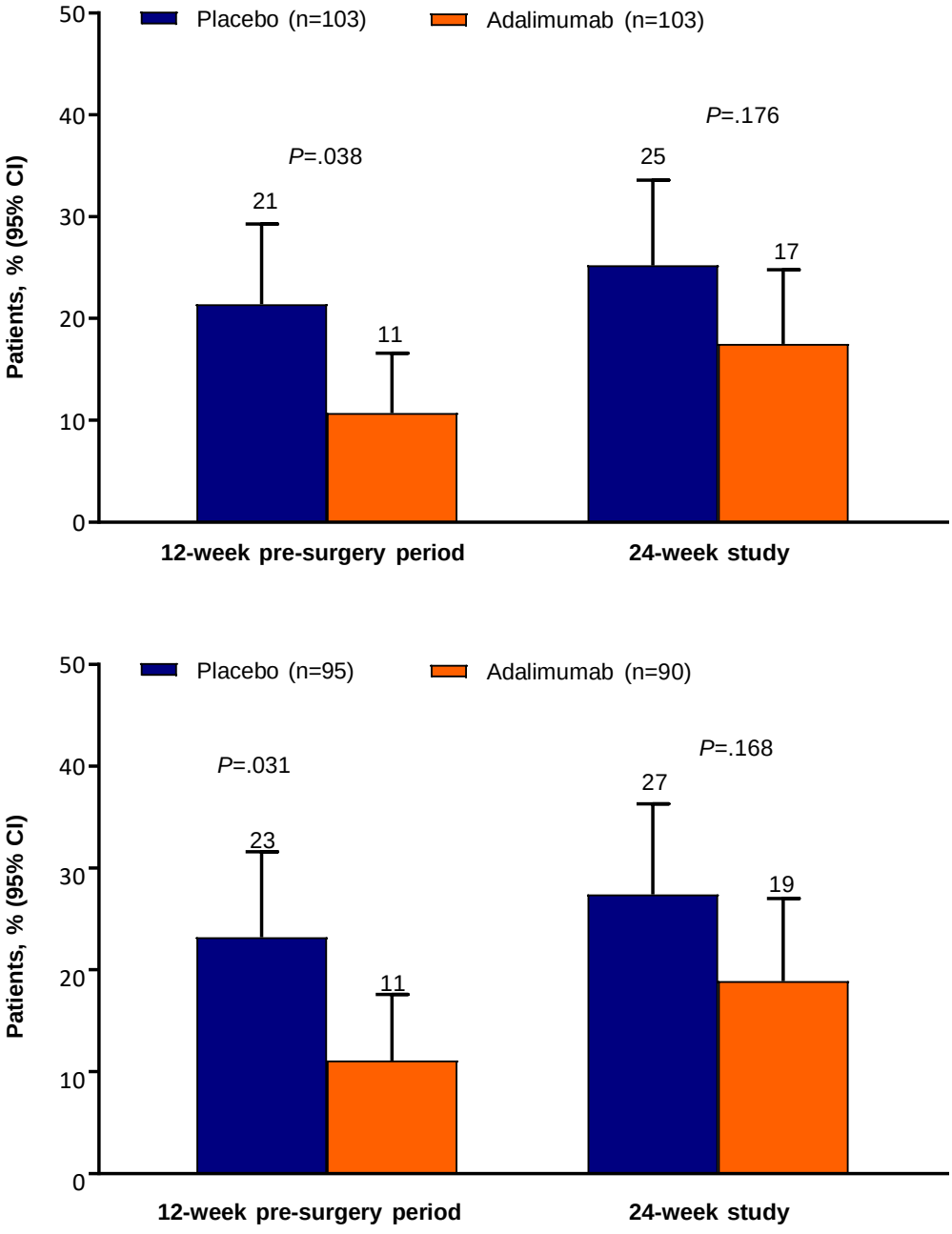
[a]No study drug was administered at week 24. EW, every week; HS, hidradenitis suppurativa.

eFigure 2. Change From Baseline in hs-CRP



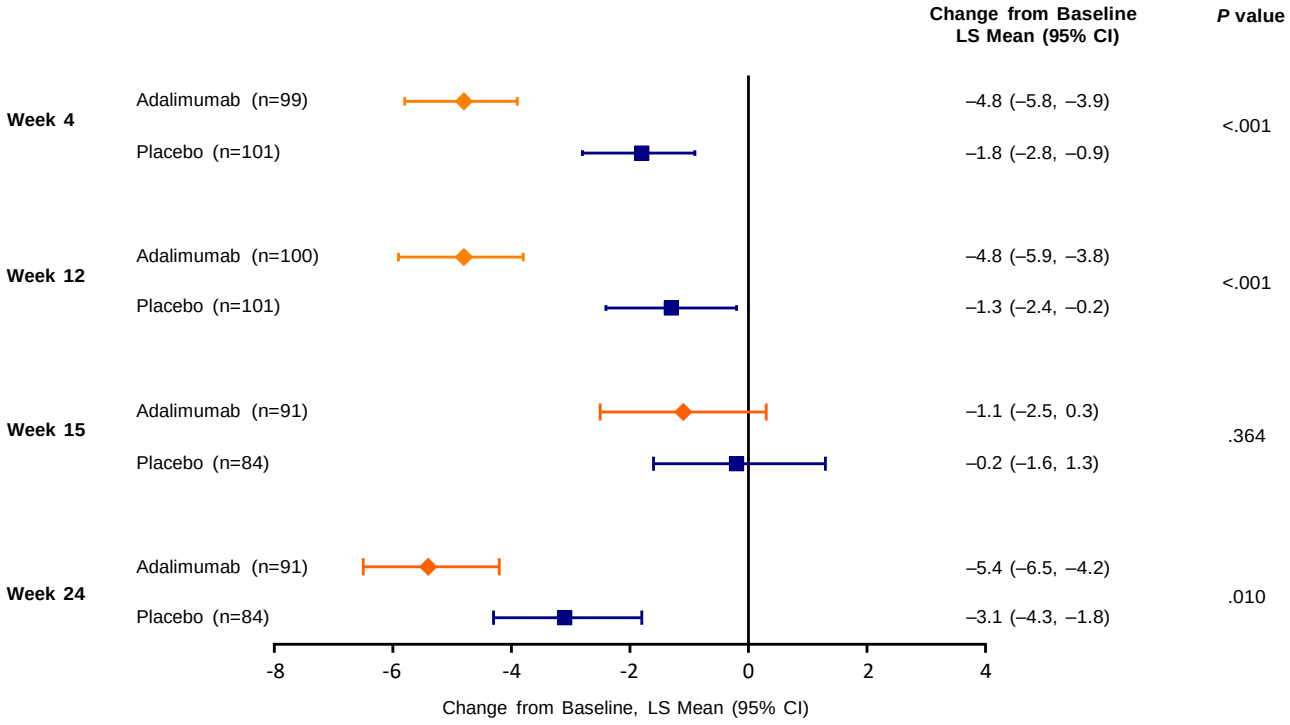
Analysis was conducted in the ITT population using an LOCF approach. Nominal *P* values without controlling for overall type-I error are shown. HS, hidradenitis suppurativa; hs-CRP, high-sensitivity C-reactive protein; ITT, intent to treat; LOCF, last observation carried forward; LS, least squares.

eFigure 3. Patients Experiencing a Flare During the 12-Week Pre- surgery Period (Across All Body Regions) and During the Entire 24-Week Study (Across Non-surgical Sites) in the (A) ITT Population and in the (B) Post Hoc Sensitivity Analyses



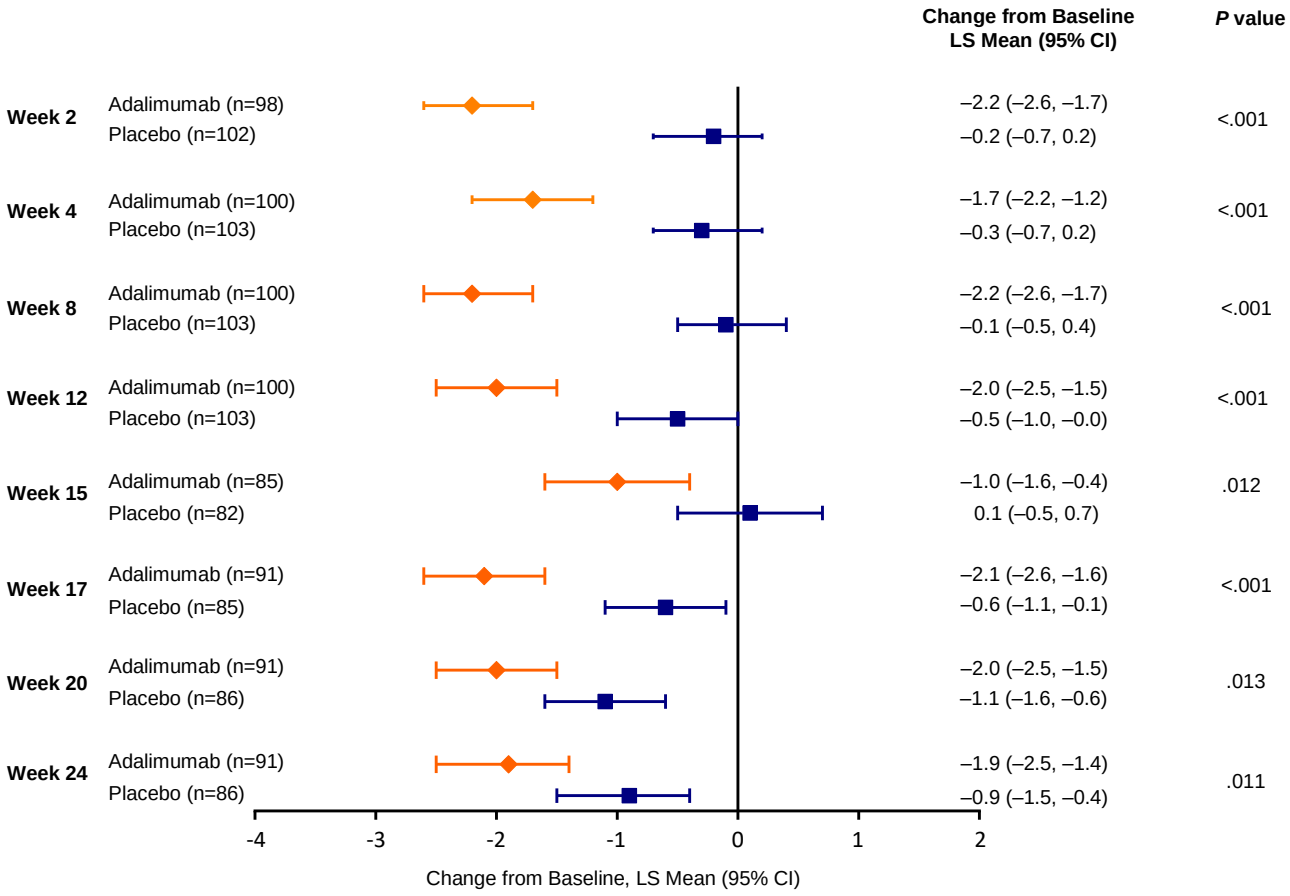
Post hoc sensitivity analyses were conducted to exclude the 21 patients with baseline AN <3 at the HS non-surgical sites (ie, did not meet the key lesion entry criterion of baseline AN count of ≥3 at the HS non-surgical site). Both panels represent NRI analyses. Nominal *P* values without controlling for overall type-I error are shown. AN, abscess and inflammatory nodule; HS, hidradenitis suppurativa; ITT, intent-to-treat; NRI, non-responder imputation.

eFigure 4. Change From Baseline in DLQI



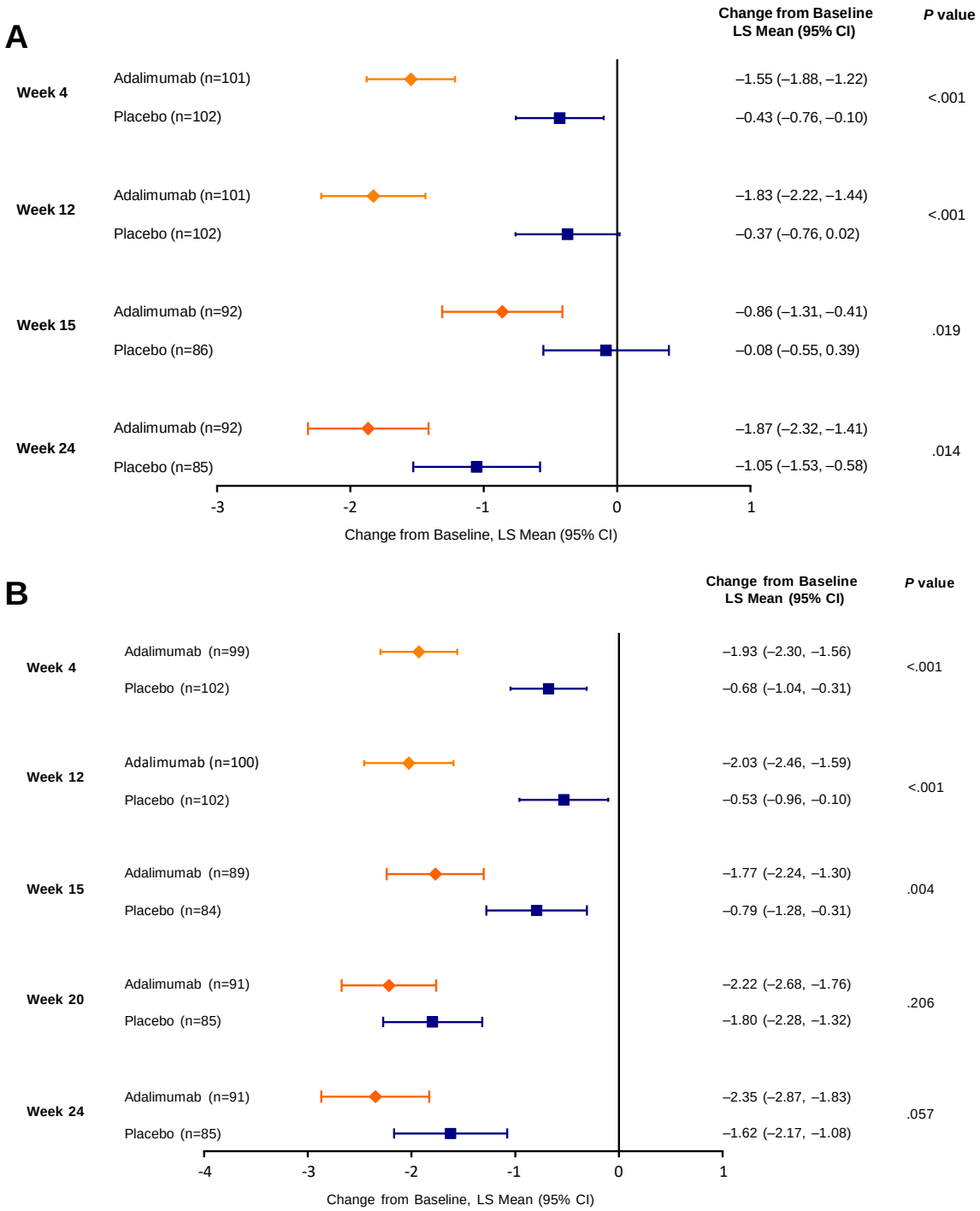
Analysis was conducted in the ITT population using an LOCF approach. Nominal *P* values without controlling for overall type-I error are shown. DLQI, dermatology life quality index; ITT, intent to treat; LOCF, last observation carried forward; LS, least squares.

eFigure 5. Change From Baseline in HS-PGA-SP



Assessment of daily skin pain at its worst due to HS was done using a numeric rating scale (0–10); negative change values indicate improvement (reduction in pain). Analysis was conducted in the ITT population using an LOCF approach. Nominal *P* values without controlling for overall type-I error are shown. HS, hidradenitis suppurativa; HS-PGA-SP, HS Patient's Global Assessment of Skin Pain; ITT, intent to treat; LOCF, last observation carried forward; LS, least squares.

eFigure 6. Change From Baseline in (A) HSIA Overall Score and (B) HSSA



Clinically meaningful improvements were defined as a decrease of 1–2 points from baseline. HSIA and HSSA were developed to assess the impact and primary symptoms of HS, respectively, in the 7 days prior to assessment. Analysis was conducted in the ITT population using an LOCF approach. Nominal *P* values without controlling for overall type-I error are shown. HS, hidradenitis suppurativa; HSIA, HS impact assessment; HSSA, HS symptoms assessment; ITT, intent to treat; LOCF, last observation carried forward; LS, least squares.