Efficacy and Safety of Guselkumab Through Week 96 After Intravenous or Subcutaneous Induction in Participants With Crohn's Disease: Phase 3 Long-term Extension Data From GALAXI 2, GALAXI 3, and GRAVITI

Scan the QR code.
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

P1099

Geert R. D'Haens,[1] David T. Rubin,[2] Anita Afzali,[3] Ailsa Hart,[4] Tadakazu Hisamatsu,[5] Nat A. Terry,[6] Mobolaji Olurinde,[6] Rian Van Rampelbergh,[7] Jacqueline Yee,[8] Wilbert van Duijnhoven,[7] Chris Corbett,[9] Elizabeth Merrall,[10] Qian Cao,[11] Remo Panaccione,[12] Julián Panés,[13] Flavio Steinwurz,[14] Silvio Danese,[15] Bruce E. Sands[16]

[1]Department of Gastroenterology, Amsterdam University Medical Centers, Amsterdam, The Netherlands; [2]University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; [3]Division of Digestive Diseases, University of Cincinnati College of Medicine, Cincinnati, OH, USA; [4]London North-West University Healthcare NHS Trust, London, UK; [5]Department of Gastroenterology and Hepatology, Kyorin University, Tokyo, Japan; [6]Johnson & Johnson, Spring House, PA, USA; [7]Johnson & Johnson, Antwerp, Belgium; [8]Johnson & Johnson, Raritan, NJ, USA; [9]Johnson & Johnson UK, High Wycombe, UK; [10]Johnson & Johnson, Leiden, The Netherlands; [11]Sir Run Run Shaw Hospital Affiliated with School of Medicine, Zhejiang University, Hangzhou, China; [12]Inflammatory Bowel Disease Unit, Division of Gastroenterology and Hepatology, University of Calgary, Calgary, AB, Canada; [13]Hospital Clínic de Barcelona, IDIBAPS, CIBERehd, Barcelona, Spain; [14]Hospital Israelita Albert Einstein, São Paulo, Brazil; [15]Gastroenterology and Endoscopy, IRCCS San Raffaele Hospital and Vita-Salute San Raffaele University, Milan, Italy; [16]Dr. Henry D Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA

Background

- Guselkumab, a dual-acting IL-23p19 subunit inhibitor, is highly efficacious in participants with Crohn's disease (CD)
- Phase 3 studies (GALAXI 2, GALAXI 3, and GRAVITI) showed that guselkumab has similar efficacy after induction and through week 48 with either intravenous (IV) or subcutaneous (SC) induction therapy (followed by SC maintenance therapy)
- Data through week 96 of these studies can help to elucidate the durability of efficacy and the longer-term safety of guselkumab in CD

Objective

- **We report guselkumab efficacy and safety data through week 96 of the GALAXI and GRAVITI studies**

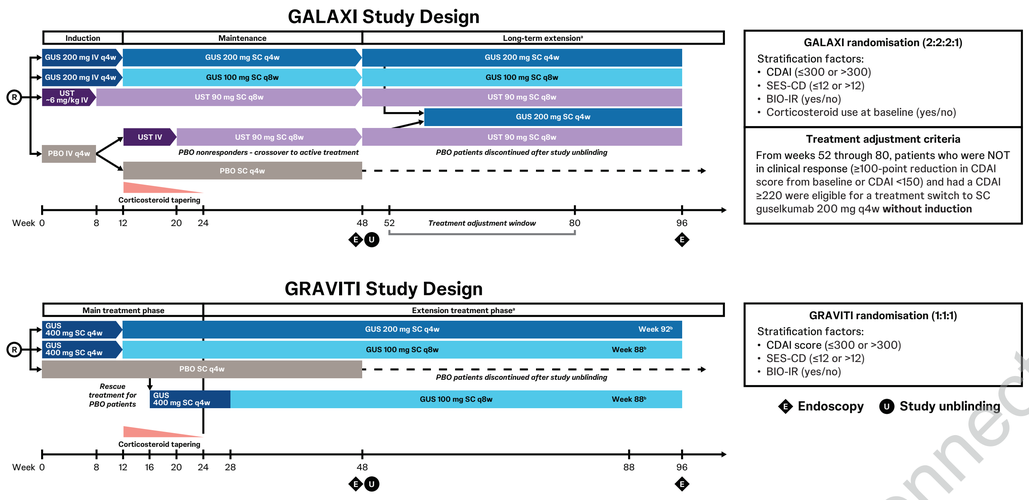
Conclusions

- **Long-term efficacy outcomes show the durability of guselkumab treatment in Crohn's disease through 2 years across multiple studies and both SC maintenance doses**
- **Long-term efficacy was similar with either guselkumab IV or SC induction followed by SC maintenance**
- **No new safety concerns were identified**

Methods

Study Methods

- Both GALAXI and GRAVITI had double-blind, placebo-controlled, treat-through designs with blinding until the week 48 analyses were completed
  - GALAXI 2 and GALAXI 3 evaluated IV guselkumab induction (200 mg at weeks 0, 4, and 8) followed by SC maintenance (100 mg every 8 weeks or 200 mg every 4 weeks)
  - GRAVITI assessed SC guselkumab induction (400 mg at weeks 0, 4, and 8) and the same guselkumab maintenance regimens used in GALAXI
- Participants entered the LTE period receiving the same maintenance treatment they received prior to the LTE
- Between weeks 52 and 80 (GALAXI only), participants who were not in clinical response dose-escalated or "sham" adjusted to 200 mg SC every 4 weeks
  - Participants receiving guselkumab 100 mg SC every 8 weeks dose-escalated to 200 mg SC every 4 weeks
  - Those receiving guselkumab 200 mg SC every 4 weeks "sham" adjusted to guselkumab 200 mg SC every 4 weeks



[a] *The present study includes data through 96 weeks.*
[b] *Denotes when last dose was received during the extension before analysis at week 96.*
***BIO**=biologics, **CD**=Crohn's disease, **CDAI**=Crohn's Disease Activity Index, **GUS**=guselkumab, **IR**=inadequate response or intolerance, **IV**=intravenous, **LTE**=long-term extension, **PBO**=placebo, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **R**=randomisation, **SC**=subcutaneous, **SES-CD**=Simple Endoscopic Score for Crohn's Disease, **UST**=ustekinumab.*

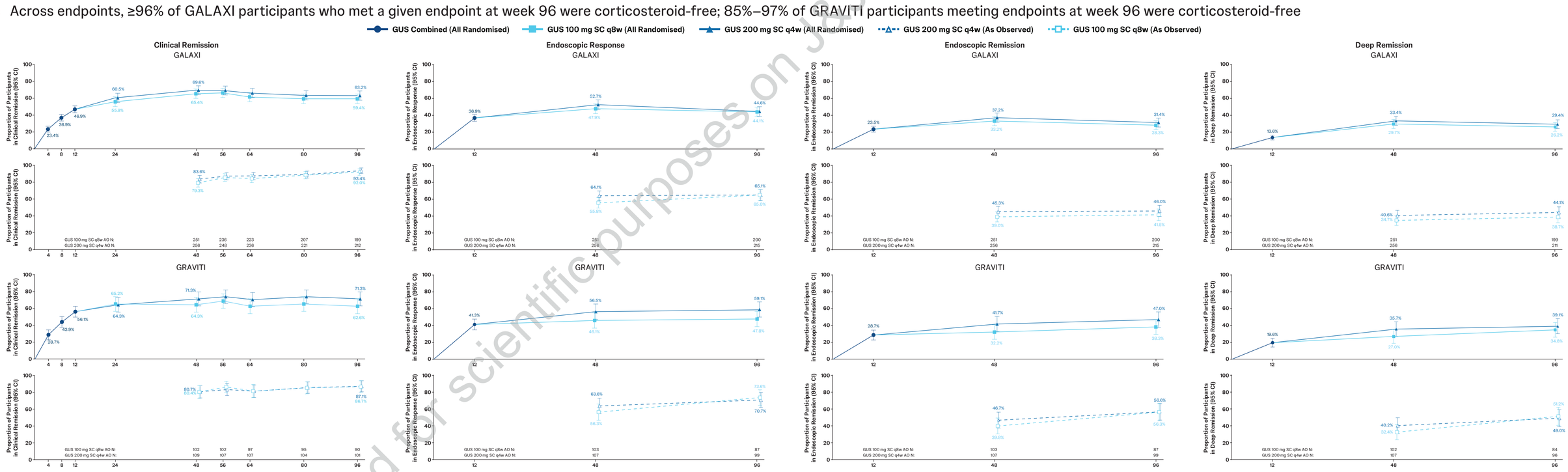
Analysis Methods

- Efficacy analyses included all participants randomised at week 0 who had an SES-CD ≥6 (or ≥4 for those with isolated ileal disease) and received at least 1 partial or complete study drug dose
- For the main efficacy analysis, non-responder imputation was used
  - Missing data, meeting treatment failure criteria, discontinuations (including not entering the LTE), and CD-related intercurrent events (including dose adjustment in GALAXI) were considered non-response
- As observed efficacy data (week 48 to week 96) are also presented
  - The as observed analysis included participants who entered the LTE, received ≥1 partial or complete study drug dose during the LTE, and had data available at the assessment timepoint; participants who had a dose adjustment (GALAXI only) were not included from the day after the date of dose adjustment
- Safety analyses comprised all randomised participants who received study drug

Results

Rates of Clinical Remission, Endoscopic Response, Endoscopic Remission, and Deep Remission Through Week 96

- Across studies, high rates of long-term endoscopic response, endoscopic remission, clinical remission, and deep remission were observed through week 96 after treatment with either guselkumab IV or SC induction followed by both SC maintenance doses
- Across endpoints, ≥96% of GALAXI participants who met a given endpoint at week 96 were corticosteroid-free; 85%–97% of GRAVITI participants meeting endpoints at week 96 were corticosteroid-free



GUS All Randomised participant numbers (all timepoints): 286 for the 100 mg SC q8w group and 296 for the 200 mg SC q4w group in GALAXI; 115 in both groups for GRAVITI. Clinical remission is defined as a CDAI score <150. Endoscopic response is defined as a ≥50% improvement in SES-CD (GALAXI/GRAVITI) or an SES-CD ≤2 (GALAXI only). Endoscopic remission is defined as an SES-CD ≤4, with a ≥2-point reduction and no subscore >1 on any subcomponent. Deep remission is defined as achieving both clinical remission and endoscopic remission.
***AO**=as observed, **CDAI**=Crohn's Disease Activity Index, **CI**=confidence interval, **LTE**=long-term extension, **N**=number, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **SC**=subcutaneous, **SES-CD**=Simple Endoscopic Score for Crohn's Disease.*

Treatment Disposition Prior to Week 96

- Between week 0 and week 96, 127/582 participants (21.8%) from GALAXI 2/GALAXI 3 and 31/230 participants (13.5%) from GRAVITI discontinued treatment

	GALAXI 2 and GALAXI 3	GRAVITI
	Combined N=582	Combined N=230
Number of pts who discontinued study treatment prior to W96	127 (21.8%)	31 (13.5%)
Reason for discontinuing study treatment		
AE - Worsening of CD	15 (2.6%)	4 (1.7%)
AE - Other	27 (4.6%)	5 (2.2%)
AE - COVID-19 related	0	0
Death	0	1 (0.4%)
Initiated prohibited medication	0	0
Lack of efficacy	31 (5.3%)	12 (5.2%)
Lost to follow-up	2 (0.3%)	2 (0.9%)
Protocol deviation	0	0
Pregnancy	4 (0.7%)	1 (0.4%)
Pt refused further study treatment	4 (0.7%)	N/A
Withdrawal by pt	31 (5.3%)	4 (1.7%)
Withdrawal by pt - COVID-19	0	0
Withdrawal by pt - Other major disruption related	1 (0.2%)	0
CD-related surgery	5 (0.9%)	1 (0.4%)
Non-responder at W20 and W24	1 (0.2%)	1 (0.4%)
PBO pts discontinuing study agent due to W48 unblinding	0	0
Other	7 (1.2%)	0

***AE**=adverse event, **CD**=Crohn's disease, **GUS**=guselkumab, **IV**=intravenous, **N**=number, **N/A**=not applicable, **PBO**=placebo, **pt**=participant, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **SC**=subcutaneous, **W**=week.*

Summary of Treatment-Emergent Adverse Events Through Week 96 for All Randomised Participants Who Received ≥1 Study Drug Dose

- Safety data through 2 years of treatment were comparable across studies and consistent with the well-characterised safety profile of the label

	GALAXI 2 and GALAXI 3 (pooled)			GRAVITI		
	Placebo[a,b] N=153	GUS 100 mg SC q8w[a,b] N=296	GUS 200 mg SC q4w[c] N=407	Placebo[d] N=117	GUS 100 mg SC q8w N=115	GUS 200 mg SC q4w N=115
Average duration of follow-up, weeks	28.5	82.1	73.2	36.4	88.6	93.3
Average exposure, number of administrations	6.5	11.0	17.7	8.4	11.9	23.0
Total patient-years of follow-up	83.4	465.5	570.9	81.7	195.2	205.7
Number of AEs	364	1374	1807	307	520	573
Number of AEs / 100 patient-years of follow-up	436.2	295.1	316.5	375.6	266.4	278.6
Number of SAEs	24	54	55	26	32	19
Number of SAEs / 100 patient-years of follow-up	28.8	11.6	9.6	31.8	16.4	9.2
Number of AEs leading to discontinuation	16	27	31	10	10	3
Number of AEs leading to discontinuation / 100 patient-years of follow-up	19.2	5.8	5.4	12.2	5.1	1.5
Number of serious infections[e]	4	3	8	0	2	1
Number of serious infections / 100 patient-years of follow-up	4.8	0.6	1.4	0	1.0	0.5

[a]*Up to dose adjustment.*
[b]*Treatment group at the start of the long-term extension period. Includes events from week 48 to the time of dose adjustment for participants who dose adjusted, and all events from week 48 through week 96 for participants who never dose adjusted.*
[c]*Participants who were randomised to receive GUS 200 mg SC q4w maintenance dosing or had a dose adjustment (including "sham") to GUS 200 mg SC q4w dosing from all treatment groups (including those randomised to placebo and ustekinumab); for participants who had a dose adjustment, only data after their first GUS 200 mg dose are included.*
[d]*Includes all placebo participants, excluding data after rescue with GUS. All participants who were on placebo treatment at the time of study unblinding after the week 48 database lock were discontinued from the study.*
[e]*Infections are based on MedDRA system organ class "Infections and Infestations."*
GALAXI adverse events are coded using MedDRA Version 27.0; GRAVITI adverse events are coded using MedDRA Version 27.1.
***AE**=adverse event, **GUS**=guselkumab, **MedDRA**=Medical Dictionary for Regulatory Activities, **q4w**=every 4 weeks, **SAE**=serious adverse event.*

PRESENTED AT: 21st Congress of the European Crohn's and Colitis Organisation (ECCO); February 18–21, 2026; Stockholm, Sweden. **ACKNOWLEDGEMENTS:** Medical writing support was provided Jen Ciarochi, PhD, under the direction of the authors, in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: GD:** advisor and/or speaker for AbbVie, Abivax, Agomab, Alimentiv, AnaptysBio, Bristol Myers Squibb, Boehringer Ingelheim, Celltrion, Eli Lilly, Galapagos, GlaxoSmithKline, Index Pharmaceuticals, Johnson & Johnson, Merck, Polpharm, Prometheus Biosciences, Sanofi, Takeda, and Tillotts. **DTR:** consulting and/or speaker fees and/or advisory board participation for AbbVie, AltruBio, Apex, Avalo, Bristol Myers Squibb, Buhlmann Diagnostics, Celgene, Connect BioPharma, Intouch Group, Iterative Health, Johnson & Johnson, Lilly, Pfizer, Samsung Neurologica, and Takeda; AltruBio, Datos Health, and Iterative Health stock options; grants from Takeda; membership on the Board of Directors of Cornerstones Health, Inc and on the Crohn's & Colitis Foundation's Board of Trustees. **AA:** consulting fees from AbbVie, Takeda, Johnson & Johnson, Bristol Myers Squibb/Celgene, Pfizer, Eli Lilly, Gilead, Diasorin, and TLL Pharmaceuticals; speaker fees from AbbVie, Takeda, Johnson & Johnson, Bristol Myers Squibb, and Pfizer; service on advisory boards for AbbVie, Takeda, Johnson & Johnson, Bristol Myers Squibb, Pfizer, Eli Lilly, and Gilead; research/education support from AbbVie, Johnson & Johnson, Pfizer, Bristol Myers Squibb, and Takeda; Co-Founder of IBD Horizons. **AH:** lecturer and/or an advisory board participation for Bristol Myers Squibb, Celltrion, Falk, AbbVie, Johnson & Johnson, Takeda, Pfizer, Galapagos, MSD, and GSK. **TH:** research grants from AbbVie GK, Boston Scientific Corporation, EA Pharma Co. Ltd., JIMRO Co. Ltd., Kissei Pharmaceutical Co. Ltd., Kyorin Pharmaceutical Co. Ltd., Mitsubishi Tanabe Pharma Corporation, Mochida Pharmaceutical Co. Ltd., Nippon Kayaku Co. Ltd., Pfizer Inc., Takeda Pharmaceutical Co. Ltd., and Zeria Pharmaceutical Co. Ltd.; consulting fees from AbbVie GK, Abivax, Bristol Myers Squibb, EA Pharma Co. Ltd., Gilead Sciences, Johnson & Johnson, Lilly, Mitsubishi Tanabe Pharma Corporation, and Pfizer Inc.; lecture fees from AbbVie GK, EA Pharma Co. Ltd., Johnson & Johnson, JIMRO Co., Kissei Pharmaceutical Co. Ltd., Kyorin Pharmaceutical Co. Ltd., Mitsubishi Tanabe Pharma Corporation, Mochida Pharmaceutical Co., Ltd., Pfizer Inc., and Takeda Pharmaceutical Co. Ltd. **NAT, MO, RVR, JY, WvD, CC,** and **EM:** employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson. **QC:** steering committee adviser for Bristol Myers Squibb and Johnson & Johnson; research grants from Takeda and Johnson & Johnson. **RP:** consultant for Abbott, AbbVie, Abivax, Alimentiv, Amgen, Arena Pharmaceuticals, AstraZeneca, Biogen, Biora Therapeutics, Inc., Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, Cosmo Pharmaceuticals, Eisai, Elan Pharmaceuticals, Eli Lilly and Company, Ferring Pharmaceuticals, Fresenius Kabi, Galapagos, Genentech (Roche), Gilead Sciences, GlaxoSmithKline, JAMP Pharma, Johnson & Johnson, Merck & Co., Inc., Novartis, Oppilan Pharma, Organon, Pandion Therapeutics, Pendopharm G.I. Solutions, Pfizer, Prometheus Biosciences, Protagonist Therapeutics Inc, Roche, Sandoz, Satisfai Health, Shire Pharma, Sublimity Therapeutics, Takeda Pharmaceuticals, Theravance Biopharma, Trellus Health, Ventyx Biosciences, Viatris, and UCB; speaker's fees from AbbVie, Amgen, Arena Pharmaceuticals, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Ferring Pharmaceuticals, Fresenius Kabi, Gilead Sciences, Johnson & Johnson, Merck & Co., Inc., Organon, Pfizer, Roche, Sandoz, Shire Pharma, and Takeda Pharmaceuticals; advisory boards for AbbVie, Alimentiv, Amgen, Arena Pharmaceuticals, AstraZeneca, Biogen, Biora Therapeutics, Inc., Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Ferring Pharmaceuticals, Fresenius Kabi, Genentech (Roche), Gilead Sciences, GlaxoSmithKline, JAMP Pharma, Johnson & Johnson, Merck & Co., Inc., Novartis, Organon, Pandion Therapeutics, Pfizer, Protagonist Therapeutics Inc, Roche, Sandoz, Shire Pharma, Sublimity Therapeutics, Takeda Pharmaceuticals, Ventyx Biosciences, and Viatris. **JP:** consultancy fees/honorarium from AbbVie, Alimentiv, Athos, Atomwise, Boehringer Ingelheim, Celsius, Ferring, Galapagos, Genentech/Roche, GlaxoSmithKline, Johnson & Johnson, Mirum, Nimbus, Pfizer, Progenity, Prometheus, Protagonist, Revolo, Sanofi, Sorriso, Surrozen, Takeda, and Wasserman; served on a data safety monitoring board for Alimentiv, Mirum, Sorriso, Sanofi, and Surrozen. **FS:** consultant, speaker, or researcher for AbbVie, Amgen, Celltrion, Ferring, Johnson & Johnson, Pfizer, Sandoz, and Takeda. **SD:** consultancy fees from AbbVie, Alimentiv, Allergan, Amgen, AstraZeneca, Athos, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Enthera, Ferring, Gilead, Hospira, Inotrem, Johnson & Johnson, MSD, Mundipharma, Mylan, Pfizer, Roche, Sandoz, Sublimity, Takeda, TiGenix, UCB, and Vifor; lecture fees from AbbVie, Amgen, Ferring, Gilead, Johnson & Johnson, Mylan, Pfizer, and Takeda. **BES:** consulting fees from AbbVie, Adiso Therapeutics, Agomab, Alimentiv, Amgen, AnaptysBio, Arena Pharmaceuticals, Artugen Therapeutics, AstraZeneca, Biologic Design, Biora Therapeutics, Boehringer Ingelheim, Celltrion, Equillium, Enthera, Enveda Biosciences, Evommune, Ferring, Fzata, Galapagos, Genentech (Roche), Gilead Sciences, GlaxoSmithKline, Gossamer Bio, Inhotex, Index Pharmaceuticals, Innovation Pharmaceuticals, Kaleido, Kallyope, Merck & Co, Microba, Microbiotica, Mitsubishi Tanabe, Mobius Care, Morphic Therapeutics, MRM Health, Nexus Therapeutics, Nimbus Discovery, Odyssey Therapeutics, OSE Immunotherapeutics, Palisade Bio, Protagonist Therapeutics, Q32 Bio, Rasayana Therapeutics, Recludix Therapeutics, Reistone Biopharma, Sanofi, Sorriso Pharmaceuticals, Spyre Therapeutics, Target RWE, Teva, TLL Pharmaceutical, TrIX, TRex Bio, Union Therapeutics, and Ventyx Biosciences; consulting and speaking fees from Abivax; consulting and speaking fees and other support from Lilly; research grants, consulting and speaking fees and other support from Bristol Myers Squibb, Johnson & Johnson, Pfizer, and Takeda; stock/stock options from Ventyx Biopharma.

This material is distributed for scientific purposes on J&J Medical Connect, and is not for promotional use