

Att:
Anders Ottenblad
Nordic Director, Office of Ethics & Compliance
AbbVie AB
Email: anders.ottenblad@abbvie.com

Solna 2026-04-28

Dear Mr. Ottenblad:

We acknowledge receipt of your cease-and-desist letter dated 14 April 2026 concerning J&J satellite symposia and commercial booth materials at the ECCO conference that was held in Stockholm in February of this year (your Letter).

Since the issues raised in your Letter pertain to an international/European congress, we take the liberty of responding to you in English.

Introduction

Like AbbVie, and in line with our company Credo and Code of Ethical Business Conduct, J&J takes **compliance very seriously** and we are committed to conducting all interactions and communications with healthcare professionals in a manner that is ethical, transparent, and consistent with applicable laws, regulations and self-regulatory frameworks, including the LIF Ethical rules. We share the importance of ensuring that any information provided is truthful, not misleading, and consistent with the approved product information and regulatory requirements.

By way of example, as far as our satellite symposia are concerned, we request our speakers and scientific committee members to apply the highest scientific standards, and for that this purpose all speakers and scientific committee members have undertaken the contractual obligation to avoid any promotion of J&J products and to focus on scientific and/or educational topics.¹

¹ Quote from our Speaker Agreement template, as used for ECCO: "**The Presentation shall not promote JANSSEN products, but shall focus on scientific and/or educational topics.** However, Speaker acknowledges and agrees that as a manufacturer of health care products, JANSSEN's activities are regulated by the competent health authorities. Should Speaker make any reference to any JANSSEN product in the Presentation, Speaker agrees that such statements, including without limitation, representations relating to the use, safety and effectiveness/performance of the JANSSEN products and/or to actual or potential clinical outcomes which have been observed or can be expected when using said products, **shall be fairly balanced.** JANSSEN offers to review the Presentation from a regulatory point of view. It is, however, understood between the Parties that it is Speaker who will determine the content of the Presentation and who will be responsible for it. As part of the Presentation, Speaker agrees to disclose to attendees that Speaker is being compensated by JANSSEN in connection with the provision of the Services." (our emphasis)
Quote from our Scientific Committee member Agreement, as used for ECCO: "Consultant agrees to devote his best diligent efforts to provide the Services as requested by JANSSEN. Consultant agrees to cooperate with JANSSEN with respect to the specific content of the Services. However Consultant acknowledges and agrees that as a manufacturer

As will be explained in more detail below, we firmly and respectfully disagree with your allegations, and we consider the challenged statements and materials to be compliant with applicable rules.

1. Satellite Symposia: alleged (on-label and off-label) promotional statements made re: guselkumab (TREMFA®)

AbbVie has comments on several aspects of the information conveyed during the symposia and considers that the symposia violate LER, in particular Articles 2, 4, and 8 of Chapter 1, Section 1. (AbbVie's Attachments 1&2)

In its Letter, AbbVie presents a vision of J&J's satellite symposia as promotional in character, misleading and imbalanced.

We firmly reject these allegations.

At the outset we want to stress that the international ECCO (European Crohn's and Colitis Organization) congress is an important international scientific congress, one of two major European congresses in this field (together with UEGW – United European Gastroenterology Week, which typically takes place in the fall). Thus the focus of the ECCO congress is to provide high quality and cutting-edge scientific insights and medical exchanges in the field of Inflammatory Bowel Diseases (notably Crohn's Disease and Ulcerative Colitis).

Contrary to what AbbVie alleges, the general introductions of our scientific symposia can never mean that all information provided during the seminars automatically becomes promotional or that the sessions must be labeled as marketing in their entirety without further analysis. Instead, AbbVie has to demonstrate - in each individual case - that a promotional claim has been made. As J&J will demonstrate below, all information provided during the seminars was scientific and not promotional.

We also note that in your Letter you persistently refer to our product by its **brand name (TREMFA)** rather than its molecule name guselkumab, in an artificial attempt to attribute a promotional character or intent to our symposia. In reality, and according to the standards applied for medical education activities, the Speakers who were engaged by J&J consistently referred to the relevant products by their **generic name (i.e. guselkumab for J&J; risankizumab for AbbVie; mirikizumab for Lilly)**.

of health care products, JANSSEN's activities are regulated by the competent health authorities. Should Consultant make any reference to any JANSSEN product while providing the Services, Consultant agrees that such statements, including without limitation, representations relating to the use, safety and effectiveness/performance of the JANSSEN products and/or to actual or potential clinical outcomes which have been observed or can be expected when using said products, shall be fairly balanced. The Services shall not promote JANSSEN products, but shall focus on scientific and/or educational topics." (our emphasis)

More in general, we are firm that neither the purpose nor the content of the satellite symposia was promotional. Quite on the contrary, the content and purpose were mere scientific education, medical exchange and discussion, in line with the applicable legal and ethical standards, and as reflected in J&J's Speaker and Scientific Committee member agreements.

We will now respond in more detail to each of your allegations related to our satellite symposia.

a) Introduction video – space theme

AbbVie states that “(i)n this case, the symposia had a clearly promotional character, for example through the use of a space/universe theme and reinforcing elements such as sound and audiovisual material.”

J&J firmly disagrees that the use of an introductory space/universe theme makes the content of the subsequent presentations by the Speakers promotional.

The introduction videos to the satellites at the ECCO congress merely reflect the fact that all HCP's are on a journey of discovery, to seek ways of improving the health of their IBD patients – i.e. the purpose of scientific exchange. The introduction did not include any reference to specific drugs or classes of drugs and was generic to the point it could be used to introduce any satellite from any company. The videos were also a signal to the audience that the meeting was about to commence, and the faculty would be starting the programme. AbbVie's suggestion that, because there is an introductory video, this is a promotional activity, should be rejected. You will agree with us that it is not uncommon for satellite symposia to commence with starting videos and sound effects to set the scene and direction of the meeting. In educational terms this is called constructive alignment and this is also why there are clear learning objectives and summaries at the beginning and end of each session.

This introduction does not in any way compromise the scientific content of the subsequent presentations; rather, it can make it easier—and more engaging—to listen to and understand.

We also point out that the space theme is a concept that J&J has been using for satellite symposia since 2020, and never before has this been raised as a legal issue, let alone has it led to any negative decision by a local court or ethical committee. It is therefore surprising and not credible that, after so many years, this established signature of J&J has suddenly, in AbbVie's view, become a theme of a promotional nature.

Moreover, as stated above, the space theme is not unique to J&J. Other companies have also used it as part of their satellites, to highlight the importance of discovery and (cutting-edge) scientific development.

By way of comparison, AbbVie also had a clear theme on their own satellite symposia on Thursday February 19, an **ocean theme**, with the title *“The IL-23i effect in IBD: **riding the wave** to durable disease control”*. The sessions followed the same theme, *“**Making a splash**: the impact of IL-23i on clinical practice”*, *“**Lasting currents**: long-term durability and safety of IL-23i”* and *“**Rising tide**: increasing real-world experience with IL-23i”*.

Neither J&J’s space theme nor Abbvie’s ocean theme – by themselves – requalify the satellite symposia as promotional activities.

b) Size of Planets

AbbVie further claims that the order and relative size in which the planets were displayed is misleading: *“The size difference misleads the reader into interpreting Tremfya as a newer, superior, more advanced product with greater efficacy. This representation is inaccurate and misleading, and J&J does not explain the meaning of the comparison.”* (Attachment 4:2)

J&J would like to respond as follows.

It is evident that the entire introduction to this seminar is explicitly framed as a timeline of development. The presenter begins by describing the history of IL-23 evolution understanding, starting metaphorically in the Stone Age and concluding in modern times, when pharmaceutical treatments targeting IL-23 became available.

In the animation, all planets initially appear in a single, solid line and are of equal size. With a visual transition, this line then unfolds into a timeline, where older products are positioned further away in space and more recent products closer to the center, with guselkumab appearing at the end of the timeline, as it is the most recently approved IL-23 inhibitor in IBD. In addition, the size of the planets reflects the number of clinical studies conducted. The presenter explicitly explains this slide by stating: *“**the guselkumab planet—it’s the biggest one because it’s the most studied.**”*

Contrary to your allegation, the presenter does not at any point claim, or imply, that guselkumab is superior, more advanced, or associated with greater efficacy than other products. Moreover, the visual representation is accompanied by a clear statement that *“The size of the planets is based on the*

order of EMA approval. This is not an exhaustive list of all clinical trials for compounds mentioned, only those influencing the approval process worldwide. For more information, please see [ClinicalTrials.gov](https://clinicaltrials.gov)

In light of the above we firmly reject your allegation that J&J claimed any clinical superiority or greater efficacy for guselkumab.

c) Alleged misleading and off-label promotion for Tremfya® in PsO (Psoriasis)/PsA (Psoriatic Arthritis)

We disagree with AbbVie's statement that including PASI data and data from the EULAR 2023 recommendations would be *"misleading and may be regarded as off-label promotion."*

First and foremost, the statements were made in the context of a scientific presentation, and neither the content nor the context was promotional in nature (let alone that it was "off-label" promotion).

Indeed, this part of the presentation represents a fictional patient case where the speaker builds the case. This specific fictional patient was previously diagnosed with PsO and experienced joint swelling (possible comorbidity to PsO known as PsA) prior to the Crohn's disease diagnosis, hence the logical reference to PASI data (which is a common scale used for measuring effectiveness of medicinal treatments for PsO patients). Furthermore, this fictional patient was an adalimumab-failure, and these PASI data demonstrated the possibility of switching from adalimumab to guselkumab. As safety is of high importance for J&J, we cannot agree that guselkumab's 5-year data (effect and durability) could have any negative impact as this patient case demands multi-disciplinary care. Altogether, this illustrates the importance of focusing on the holistic patient when deciding on the next treatment option.

In addition, the discussion referred to the recommended dosing regimen as set out in the SmPC. Specifically, the recommended maintenance dose is 100 mg administered subcutaneously every 8 weeks for both PsO, PsA, ulcerative colitis and Crohn's disease. The information that was shared is therefore a factual description of the SmPC-recommended maintenance dosing schedule. Given the explicit reference to the SmPC-recommended maintenance regimen, **we strongly disagree that the material is misleading or that it would constitute off-label promotion.**

d) Alleged exclusive focus on guselkumab and its "positive" aspects, with minimal information on its safety profile – alleged lack of objective, factual and balanced content

We firmly disagree with AbbVie's allegation that the content of the two symposia was neither objective, factual, nor balanced and that the symposia

focused exclusively on “positive” aspects and included minimal information on guselkumab’s safety profile.

The presentations struck a correct balance between efficacy aspects of guselkumab and its safety profile. In the satellite symposium related to UC we had 3 slides that cover safety and in the Crohn’s disease satellite there were two slides dealing with safety aspects. By way of comparison, the AbbVie satellites at ECCO had a total of 2 slides on safety, one for UC and one for CD.

It is therefore incorrect to say that the symposia had minimal safety information

In addition, as far as the alleged lack of objective, factual and balanced content is concerned, we firmly counter the impression you try to create in your Letter as if the satellite symposia were (quasi)exclusively focused on guselkumab. This was not the case. In reality more than 50% of the slides in UC satellite and more than 50% of the slides in CD satellite were not specifically dedicated to guselkumab.

Furthermore, we want to emphasize that - amongst other things - both J&J satellites explained in scientific terms how a molecule like guselkumab can be used in a real-world setting, as this is definitely a question that keeps practitioners busy. This was done by presenting different cases and elaborating on patient populations, dosage selection, etc., based on data from J&J clinical trials.

The way in which guselkumab data were presented, was not dissimilar from how Risankizumab data were presented in AbbVie’s satellites. In particular we note that AbbVie’s speaker regularly used terms such as “*quite impressive results*”, “*You see very high rates*”, “*You see all these rates are high*”, “*You see HIGH RATES of clinical remission*”, “*You see a really “Staggeringly high” remission at the end of induction*”, “*All these rates of clinical remission are really high*”, “*Cs free remission at month... all really impressive*”.

In conclusion we firmly reject any allegation or suggestion that our satellite symposia were a disguised form of “promotion” for our brand.

e) Alleged off-label promotion for Tremfya® for pregnant women

J&J also denies AbbVie’s allegation that the Speaker engaged in off-label promotion for guselkumab for pregnant women.

As explained earlier, the content and intent of the presentation were merely scientific exchange. The presentation was not promotional (let alone off-label promotion).

In her presentation, the Speaker explained that a **global consensus has been established**, while at the same time making it clear that **this consensus is not reflected in the SmPC for any of the products** (at present, and possibly never).

She emphasized that the global consensus applies to **all currently approved IL-23 inhibitors**, following a review of available real-world evidence (RWE) data. This is also clearly stated in the footnote on the slide presenting RWE data for guselkumab in pregnancy, which explicitly notes that this information **is not in accordance with the SmPC** and that **guselkumab is not recommended for use during pregnancy**. See two slides below:

Clinical guidance on the management of IBD during pregnancy

*Journal of Crohn's and Colitis, 2025, 19(1), jia129
https://doi.org/10.1093/ecco-jcc/jia129
Original Article*

Global Consensus Statement on the Management of Pregnancy in Inflammatory Bowel Disease

Uma Mahadevan,¹ Cynthia H. Seow,² Edward L. Barnes,³ Maria Chaparro,⁴ Emma Flanagan,⁵ Sonia Friedman,⁶ Mette Julsgaard,⁷ Sunanda Kane,⁸ Siew Ng,⁹ Joana Torres,¹⁰ Gillian Watermeyer,¹¹ Jesus Yamamoto-Furusho,¹² Christopher Robinson,¹³ Susan Fisher,¹⁴ Phil Anderson,¹⁵ Richard Geary,¹⁶ Dana Duricova,¹⁷ Maria Dubinsky,¹⁸ Millie Long,³ and the Global Consensus Group for Pregnancy and IBD

Key Points:

- Reduced fertility with active disease and IPAA
- No risk of flare with oocyte retrieval
- Increased risk of pre-term delivery
- Increased risk of spontaneous abortion with active disease
- Increased risk of VTE

Clinical Guidance:

- Continue all biologics and thiopurines throughout pregnancy and lactation
- Avoid small molecules during pregnancy and lactation
- Provide preconception counseling to improve outcomes
- Provide low dose aspirin to reduce pre-term preeclampsia
- Perform a cesarean section for delivery if active perianal fistula, rectovaginal fistula, IPAA

'Women with IBD who are pregnant or attempting conception should continue anti-IL-23 therapy throughout pregnancy (mirikizumab, risankizumab, guselkumab)'

Johnson & Johnson
IL, interleukin; IPAA ileal pouch-anal anastomosis; VTE, venous thromboembolism.
Mahadevan U, et al. J Crohn's Colitis. 2025;19(1):jia129.

Medical Education

In a global safety database, pregnancy outcomes with guselkumab are similar to the US general population

New data at ECCO 2026!
Mahadevan U, et al.

Patient background

- Moderate-to-severe CD
- Biologic-naïve

Patient treatment goals

- Avoid corticosteroid use
- Provide effective disease control early
- Take into account life goals

Rates of pregnancy outcomes for pregnancy events with maternal exposure to guselkumab compared to the US general population¹

Category	Live birth without congenital abnormality (%)	Elective/induced abortion (%)	Spontaneous abortion (%)	Live birth with congenital abnormality (%)
Guselkumab all cases	65.0	9.0	21.0	1.5
Guselkumab prospective cases	69.2	11.7	16.7	0
Guselkumab retrospective cases	63.2	7.9	22.9	2.1
US general population	64.9	18.1	17.1	3.0

■ Live birth without congenital abnormality ■ Elective/induced abortion ■ Spontaneous abortion ■ Live birth with congenital abnormality

- 1,126 pregnancy events were reported
- This analysis focuses on the 400 pregnancy events with known outcomes; 120 were reported prospectively, 280 were reported retrospectively

Johnson & Johnson
There are limited data from the use of guselkumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition, or postnatal development. As a precautionary measure, it is preferable to avoid the use of guselkumab during pregnancy.
1. Mahadevan U, et al. Presented at ECCO 2026, P1042. 2. Guselkumab Summary of Product Characteristics (SmPC). Accessed 2026 Feb 6.

Medical Education

The second slide, based on RWE and internal safety data, solely **illustrated, from a scientific perspective**, the basis of the global consensus publication. RWE or data on file for the other IL-23 inhibitors could not be presented, as comparable data are not available to J&J in the same manner. This being said, the Speaker clearly stated that this outcome was equal to all IL-23 inhibitors, and not to guselkumab only.

In this instance, the speakers chose to elaborate freely based on their own clinical experience. This occurred on their own initiative, and without instruction

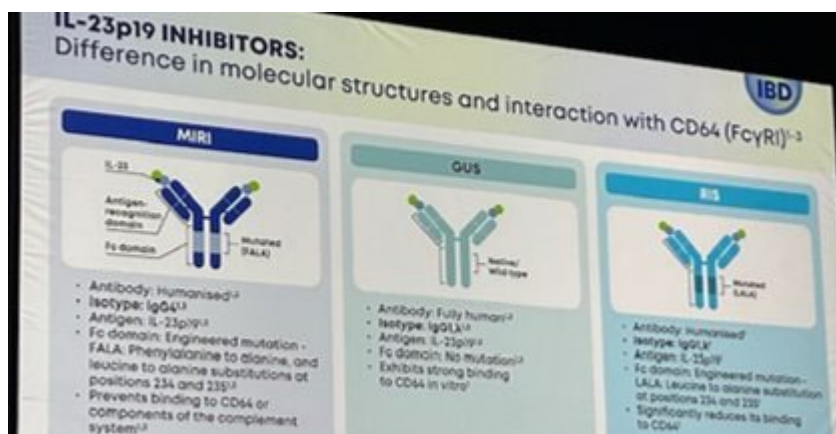
by J&J. As a reminder, our Speaker Agreements stipulate that HCPs speaking at our satellite symposia should make statements that are fair, balanced and scientific and they should not engage in promotion, let alone off-label promotion.

While we disagree with your qualification of the statements as off-label promotion, we will – without prejudice - inform the relevant speakers of the challenges you presented and will urge them going forward to use even more caution when discussing clinical practice.

f) Alleged suggestion of clinical superiority of Tremfya due its dual-binding Mechanism of Action

We strongly disagree that any clinical superiority of guselkumab was claimed or suggested based on the dual-acting nature of guselkumab's mechanism of action, i.e., the fact that in vitro data has shown that guselkumab 1) blocks IL-23 and 2) binding to CD64.

When discussing the mechanism of action of the three IL-inhibitors currently commercially available for IBD, the speaker explained the scientific rationale behind the choice of Fc domains for guselkumab, risankizumab and mirikizumab based on the common scientific knowledge at the time of design/development of the drugs. Thereby, the differences between all three IL-23 inhibitors listed by the speaker are not based on superiority for one drug over the other, but a clarification of structural differences among them, as supported by scientific evidence, including SmPC's. By way of comparison: Eli Lilly made a similar presentation about the (differences in the) MoA of the various IL-23 inhibitors during an ECCO satellite. See:



Importantly, the presentation given during the J&J satellite clearly and consistently communicated that the data relating to dual-acting (i.e. blocking IL-23 and binding to CD64) are **derived from in vitro studies** and that the **clinical relevance of this finding is currently unknown**. This limitation was explicitly stated both visually and verbally:

- 9

mislead attendees of the satellite symposia into believing a clinical advantage may exist in favor of guselkumab vs other IL-23 inhibitors.

g) Alleged misleading / promotional efficacy claims

As far as the alleged use of images with promotional and misleading headings is concerned (for CD; *“With guselkumab, >90% of patients in clinical remission at Week 48 also were corticosteroid-free for 90 days.”* for UC: *“Up to 99% of BOI/JAKi-naïve patients are in corticosteroid-free clinical remission after 1 year of treatment with guselkumab.”*) we would like to answer as follows.

What AbbVie fails to mention or recognize with regard to the first statement (re: clinical remission at Week 48 + corticosteroid-free for 90 days in CD) is that the GALAXI study (related to CD) has a treat-through design which means, by definition, that all patients (and not only the induction responders) continue until the end of the study.

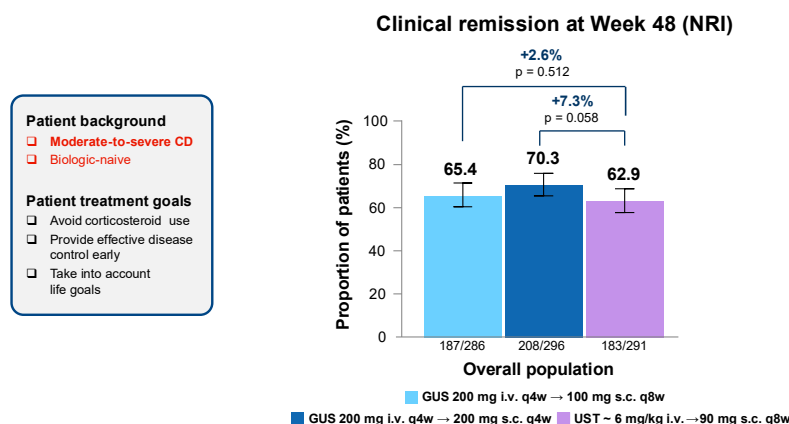
As for the second statement (re: corticosteroid-free clinical remission after 1 year in UC), the data presented by the Speaker originate from the QUASAR registrational trial for UC. All data were referenced and J&J also recorded the number of patients per group. As per the graph, shown by the speaker, and even when using the NRI analysis (which is known as the most stringent), 99% of BOI/JAKi-naïve patients were in corticosteroid-free remission.

To understand the studies and messages, the audience were presented 2 separate slides in each satellite, building on each other, not as a single slide as in Attachment 4:3 from AbbVie. These 2 slides are reproduced here:

1) CD SATELLITE (2 slides)

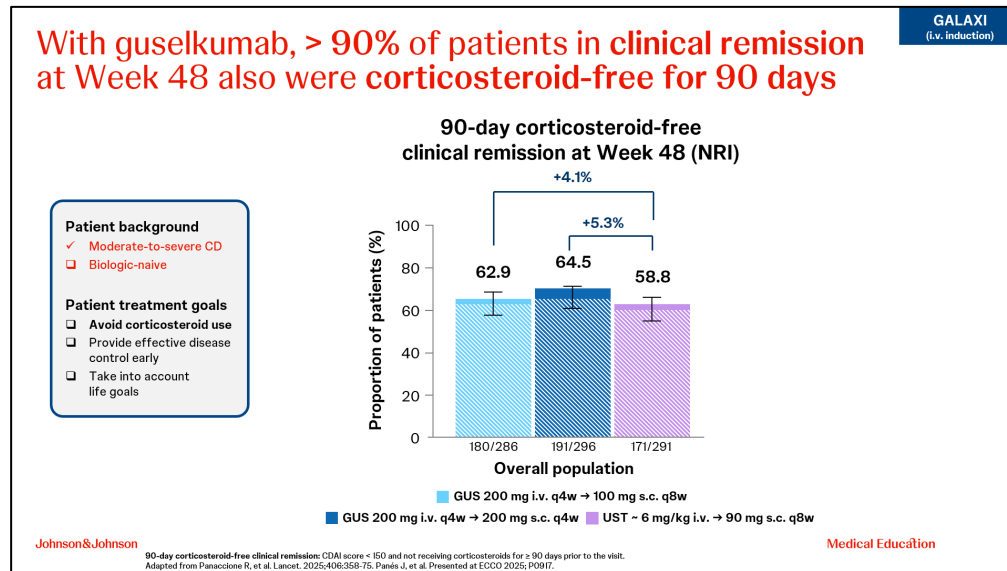
Up to 70% of patients achieved clinical remission with guselkumab at 1 year of treatment

GALAXI
(i.v. induction)

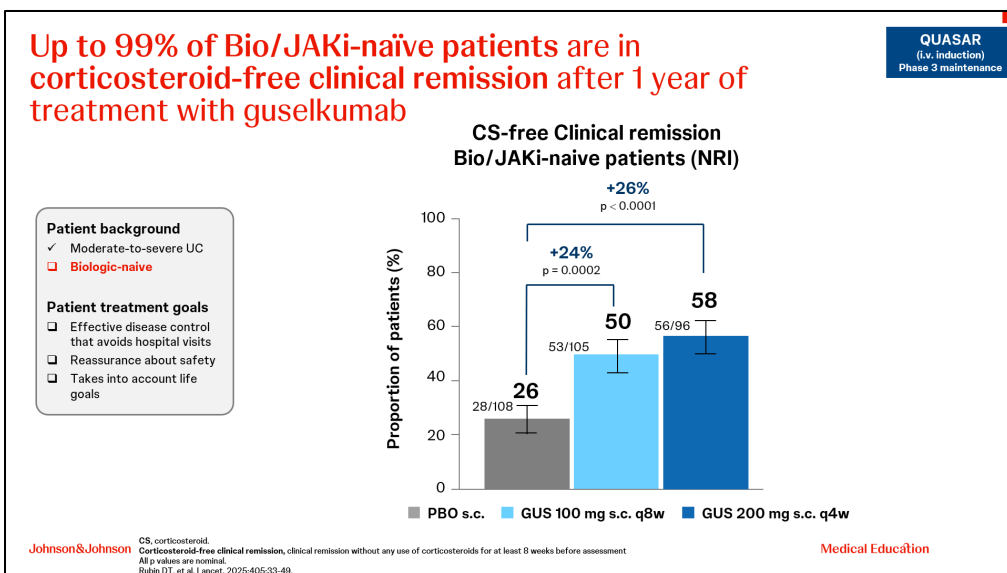


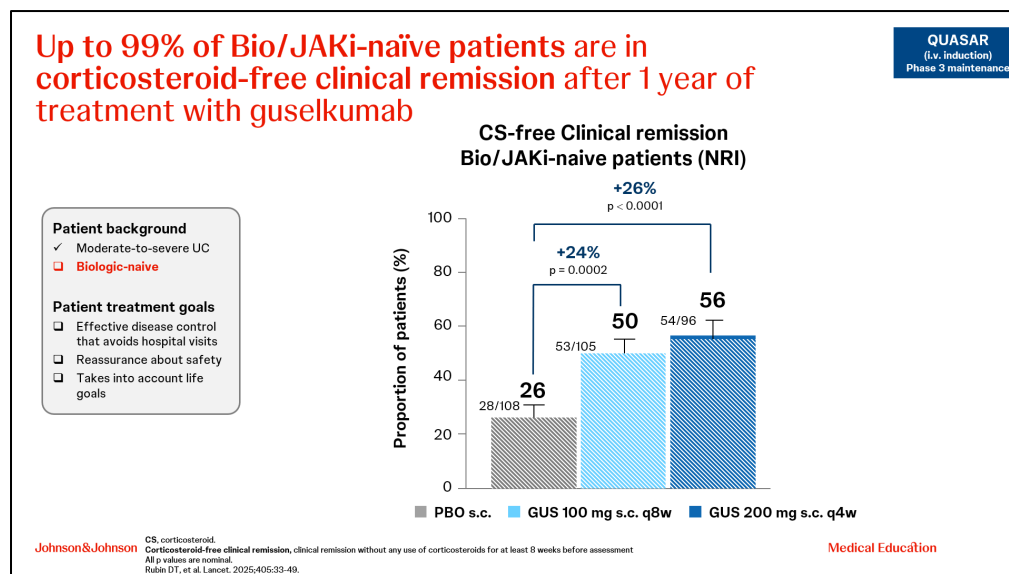
Johnson&Johnson Clinical remission CDAI < 150.
CDAI, Crohn's Disease Activity Index; GUS, guselkumab; i.v., intravenous; NRI, nonresponder imputation; q4/8w, every 4/8 weeks; s.c., subcutaneous; UST, ustekinumab.
Adapted from Panaccione R, et al. Lancet. 2025;406:358-75.

Medical Education



2) UC SATELLITE (2 slides)





Based on the above, we are confident that the audience has not at all been misled about the design or results of the GALAXI and/or QUASAR study. The data presented by the speaker accurately reflected and explained the design and outcomes and cannot be qualified as promotion, let alone misleading promotion.

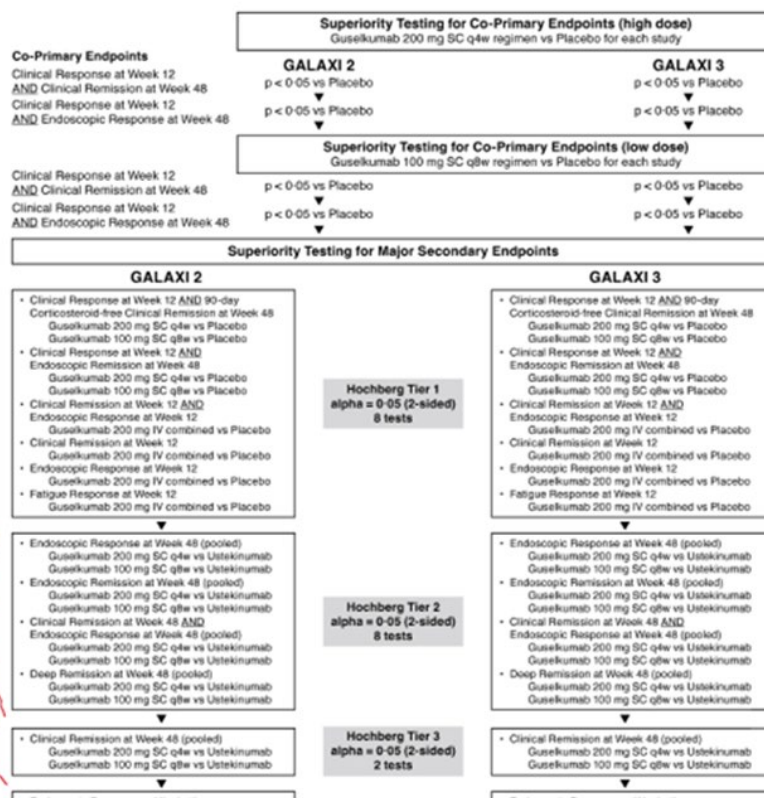
h) On superiority of guselkumab vs ustekinumab in endoscopy-driven endpoints

We disagree with your allegation that "Guselkumab did not achieve superiority versus ustekinumab in clinical remission, and therefore subsequent endpoints were not tested for statistical significance"

In the GALAXI trials Guselkumab has shown superiority vs ustekinumab in endoscopy-driven endpoints at Week 48 in a double-blind head-to-head study (Panaccione R, et al. Lancet. 2025;406:358-75).

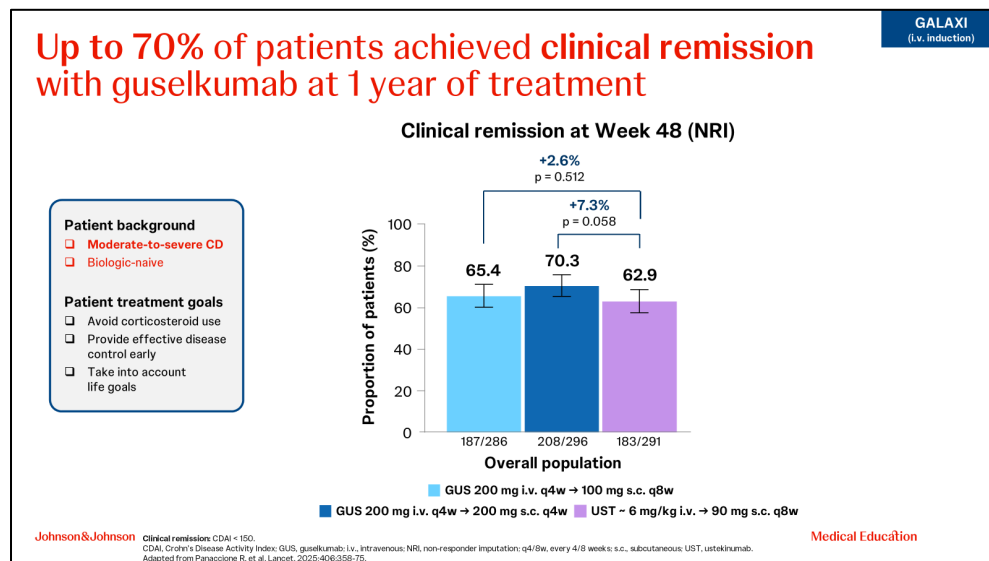
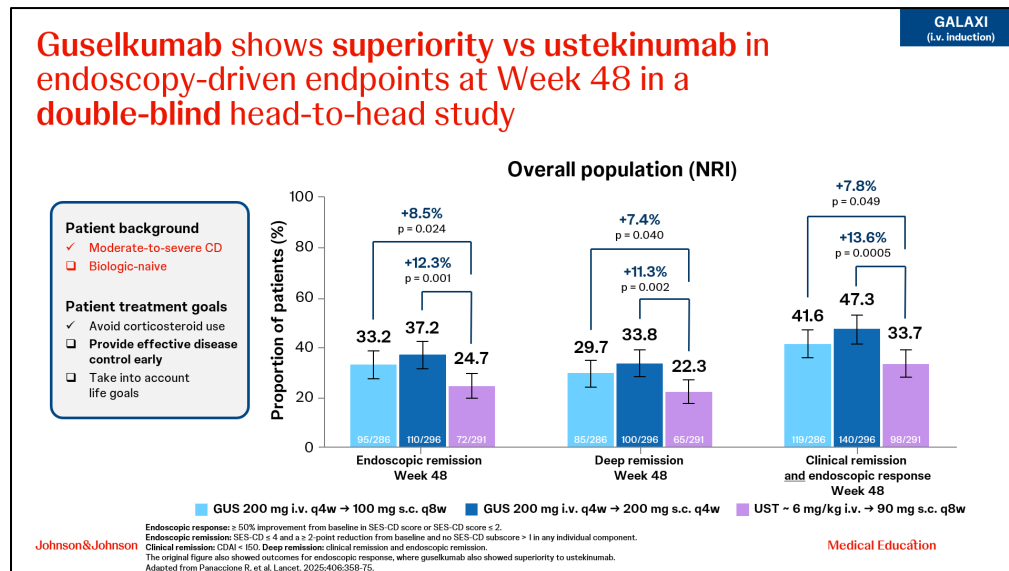
We specifically draw your attention to the following data from the Panaccione article

Endpoints testing procedure



The data marked with red show that all **endoscopic endpoints** are ahead of **clinical remission** in the hierarchical testing. This explains the statement about **superiority vs Ustekinumab in endoscopy driven endpoints**, and it clearly **contradicts your erroneous statement**.

Indeed, the head-to-head comparisons of guselkumab with ustekinumab at week 48 were first assessed in the pooled GALAXI-2 and GALAXI-3 dataset and then in each study individually. These long-term major secondary endpoints were endoscopic response at week 48, endoscopic remission at week 48, the composite of clinical remission at week 48 and endoscopic response at week 48, deep remission at week 48 (the composite of clinical remission at week 48 and endoscopic remission at week 48), and clinical remission at week 48. Both dose regimens of guselkumab were also superior to ustekinumab at week 48 in prespecified, multiplicity-controlled, treat-through analyses of the pooled GALAXI-2 and GALAXI-3 as per Panaccione R, et al. *Lancet* 2025;406:358–375. See these slides:



i) Alleged engagement of Speakers for promotional purposes

As explained above, J&J places high importance on compliance with legal and ethical rules, including those applicable to medical congresses. The adherence to these principles has also been baked into our Speaker Agreements. J&J engages external experts at international scientific congresses, in line with LER principles. J&J engages **recognized experts in the field based on their scientific competence and experience**, with the objective of enabling high-quality, evidence-based scientific exchange.

While J&J is responsible for ensuring that symposium content is **balanced, accurate, and compliant with applicable regulations**, external experts participate in their capacity as independent scientific specialists. In accordance with established ethical frameworks, companies should not seek unduly

influence or suppress an expert's legitimate scientific opinion, provided that the overall content remains non-promotional and aligned with approved product information.

During the symposia at ECCO it happened that although some slides did not mention any specific product, or the entire group of IL-23 inhibitors, speakers chose to elaborate freely based on their own clinical experience. J&J cannot interfere with the integrity of contracted speakers performing live on stage; therefore, the personal experience of a world class key opinion leader might shine through without J&J interference.

AbbVie reproduces quotes from the speakers taken from transcripts during the symposium (AbbVie's attachments 2 and 3). This can be misleading as they are single lines taken out of context. These messages should be seen in their complete context, through the eyes and ears of an audience who has been following the symposium through-out. J&J is confident that the audience has not interpreted the messages as being misleading, unbalanced, unscientific, or promotional.

All participants, regardless of whether they are clinicians or coming from the pharmaceutical industry, want to learn from the most experienced and published experts, all for the benefit of patients.

The alternative—refraining from engaging the most experienced key opinion leaders or censuring their oral presentations—would risk limiting the scientific level of discussion at major international scientific congresses. Such an approach could be counterproductive to the purpose of these forums, which is to advance medical science and clinical understanding, leading to better treatments for patients.

Finally, as shown above, J&J notes that the content, tone and balance of its satellite symposia is not dissimilar from AbbVie's satellites (see above: numerous positive quotes on Risankizumab; no verbal mention of open label nature of in-vitro study, etc.).

2. Observations regarding the commercial exhibition booth

a) Alleged misleading advertising related to CD64

Contrary to Abbvie's assertion *that "no reservations were included stating that the data were in vitro"*, the video in the commercial booth included the following footnote throughout the relevant segment: ***"Based on in vitro studies in an inflammatory monocyte model. The clinical significance of these findings is unknown."***

This statement was included specifically to ensure the audience understood the evidence basis (in vitro) and that clinical relevance in humans has not been established.

The CD64 binding was not presented as evidence of clinical benefit, nor as a claim of superiority over other IL-23 inhibitors. Given the explicit disclaimer above, we do not agree that the material would mislead visitors into believing a proven clinical advantage exists.

The statement is fully in line with section 5.1 (Mechanism of Action) of the Tremfya® SmPC. It is also fully in line with the messages that J&J has consistently used since the launch of Tremfya® in UC/CD and with the assurances provided earlier by our EMEA Medical Affairs representative Dr. Graham in his exchange with his counterparts at AbbVie Europe. In that respect we also note that in recent correspondence (April 9) your European affiliate AbbVie Europe explicitly agreed that the (continued) promotion of the dual-acting mechanistic properties of guselkumab, in combination with a clear in-vitro statement (that disclaims any link with efficacy), does not raise issues. We can but notice that your Letter directly goes against the position taken by your European HQ, which raises doubts as to the seriousness of your allegations.

b) Alleged misleading claims re: dosing frequency

In your Letter you claim that visitors of our commercial booth are given the impression that after induction Tremfya can generally be dosed six times per year and that this would not be supported by the Tremfya SmPC.

This allegation is clearly incorrect, because the **recommended maintenance dose** as set out in the Tremfya SmPC is 100 mg administered subcutaneously every 8 weeks, which corresponds to six administrations per year during maintenance therapy. The claim is therefore a factual description of the SmPC-recommended maintenance dosing schedule. Given the explicit reference to the SmPC-recommended maintenance regimen, we do not agree that the material is misleading. Furthermore, on the screen a PushPen is depicted with its characteristic green needle shield, specifically for 100 mg dosing.

Furthermore, and somewhat contradictory to your earlier allegation that the 6 injections per year (for maintenance) would not be supported by the SmPC, you allege that J&J did not clarify in the booth messaging that six-times-per-year dosing applies only to the 100 mg dose, not the higher 200 mg dose.

Again, this is incorrect. The commercial booth panel did explain, in line with the Tremfya SmPC, that for certain patients who do not show sufficient therapeutic benefit from induction therapy, an alternative maintenance regimen of 200 mg subcutaneously every 4 weeks may be considered. See the text in the asterisk "*For patients who do not show adequate therapeutic benefit to induction treatment according to clinical judgement, a maintenance dose of 200mg SC Q4w may be considered*" (+ reference to the SmPC)

We trust the above responses address the points raised in your Letter and we would appreciate your confirmation within 14 calendar days. We are also open for further Medical-to-Medical discussion should you wish to entertain such discussion.

The present letter is addressed to you without prejudice and with reservation of all rights, in particular the right to issue a separate complaint or initiate legal proceedings related to statements made at AbbVie's symposia and/or booth materials at ECCO.

Martin
Johansson



Digitally signed by
Martin Johansson
Date: 2026.04.28
15:56:05 +02'00'

Martin Johansson

Medical Affairs Lead, Sweden
Johnson & Johnson Innovative Medicine
Janssen-Cilag AB