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SAFETY OF GUSELKUMAB IN PATIENTS AGED ≥60 YEARS WITH IMMUNE-MEDIATED INFLAMMATORY DISEASES: A POOLED ANALYSIS OF REGISTRATIONAL TRIALS IN UC, CD, PSA AND PSO

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SPEAKER DISCLOSURE

Adam S. Faye

I disclose the following financial relationships with a commercial interest:

- CONSULTING: AbbVie, Eli Lilly, and Takeda.

Background and Objective

Demographics of inflammatory diseases

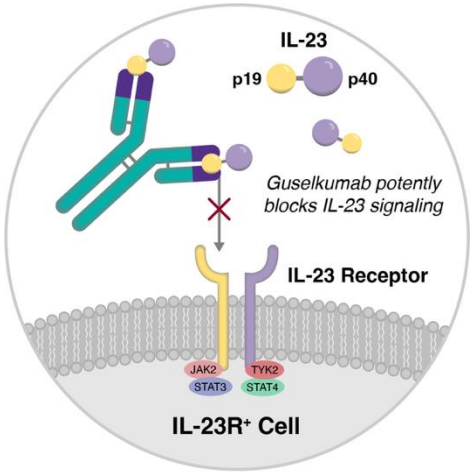
- Adults aged ≥60 years represent a large and growing proportion of patients with immune-mediated inflammatory diseases[1,2]
- Safety data for advanced therapies in this high-risk population remain limited[3]

Guselkumab (GUS)

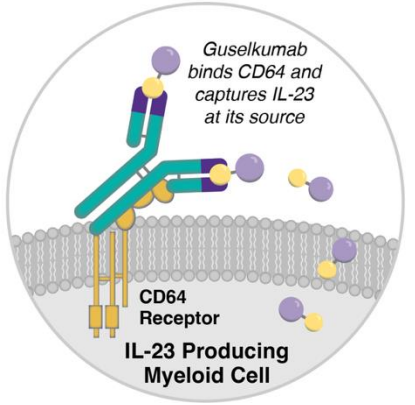
- Fully human, dual-acting interleukin (IL)-23 inhibitor that selectively targets the p19 subunit and binds to CD64 on immune cells[4]
- Approved for the treatment of Crohn's disease (CD), ulcerative colitis (UC), psoriasis (PsO) and psoriatic arthritis (PsA)[5]

Objective

- Evaluate the safety of GUS up to 1 year in patients aged ≥60 years pooled from 14 phase 2/3 randomized-controlled trials (RCTs)



Dual-acting IL-23 Inhibitor



1. Su QY. *Front Public Health.* 2025; 13: 1527680. **2.** Caron B. *J Crohns Colitis.* 2024; 18: ii3-15. **3.** Zazzara MB. *Eur Geriatr Med.* 2021; 12: 463-73. **4.** Sachen K. *Front Immunol.* 2025; 1532852. **5.** Tremfya (guselkumab) [Prescribing Information]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761061s027lbl.pdf. Accessed March 2026.

Analysis Cohort and Outcomes

Analysis Cohort

- Data were pooled from 14 phase 2/3 RCTs of GUS in PsA, PsO, UC, and CD
- Adults who received ≥1 dose of study treatment were included

Outcomes

- Pooled safety data from RCTs were analyzed through up to 1 year
  - **By age:**
    - ≥60 years of age
    - Overall population
  - **By indication:**
    - IBD: UC and CD
    - All indications: PsA, PsO, UC, CD
- Exposure-adjusted incidence rates of treatment-emergent adverse events were reported per 100 patient-years (PY) with 95% confidence intervals (CI)

Trial ID[a]	Name	Indication	Data Analyzed
NCT03162796	DISCOVER-1	PsA	Up to W60
NCT03158285	DISCOVER-2	PsA	Up to W52
NCT02319759	PsA Phase 2	PsA	Up to W54
NCT02203032	NAVIGATE	PsO	Up to W52
NCT02207231	VOYAGE 1	PsO	Up to W52
NCT02207244	VOYAGE 2	PsO	Up to W52
NCT01483599	X-PLORE	PsO	Up to W52
NCT05528510	ASTRO	UC	Up to W24
NCT04033445	QUASAR	UC	Up to W20, W32 or W44[b]
NCT03662542	VEGA	UC	Up to W38[c]
NCT03466411	GALAXI 1	CD	Up to W48
NCT03466411	GALAXI 2	CD	Up to W48
NCT03466411	GALAXI 3	CD	Up to W48
NCT05197049	GRAVITI	CD	Up to W48

[a]All trials except those highlighted in darker grey had treat-through designs. [b]Depending on entry or treatment status. [c]Monotherapy arm only. **CD**=Crohn's disease, **GUS**=guselkumab, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **RCT**=randomized-controlled trial, **UC**=ulcerative colitis, **W**=week.

Baseline characteristics were generally balanced across treatment, age, and indication groups

Baseline Characteristics by Age Group and Indication		Patients aged ≥60 years				Overall population			
		IBD[a]		All indications[b]		IBD[a]		All indications[b]	
		GUS (N=238)	PBO (N=98)	GUS (N=618)	PBO (N=212)	GUS (N=2388)	PBO (N=1025)	GUS (N=5379)	PBO (N=1910)
Demographics									
	Age, years	66.1 (5.2)	66.1 (4.9)	65.3 (4.6)	65.3 (4.5)	39.5 (13.9)	39.0 (13.6)	42.6 (13.3)	42.0 (13.4)
	Race, Asian/Black/White	16%/1%/77%	16%/0%/76%	9%/1%/88%	9%/0%/87%	22%/2%/72%	22%/2%/71%	14%/1%/82%	15%/2%/80%
Indication									
	CD	35%	20%	14%	9%	46%	33%	20%	18%
	UC	65%	80%	25%	37%	54%	67%	24%	36%
	PsD	-	-	61%	54%	-	-	56%	46%

Data is shown as mean (standard deviation) unless otherwise indicated. [a]Includes UC and CD phase 2/3 GUS RCTs. [b]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **PBO**=placebo, **PsD**=psoriatic disease, **RCT**=randomized-controlled trial, **UC**=ulcerative colitis.

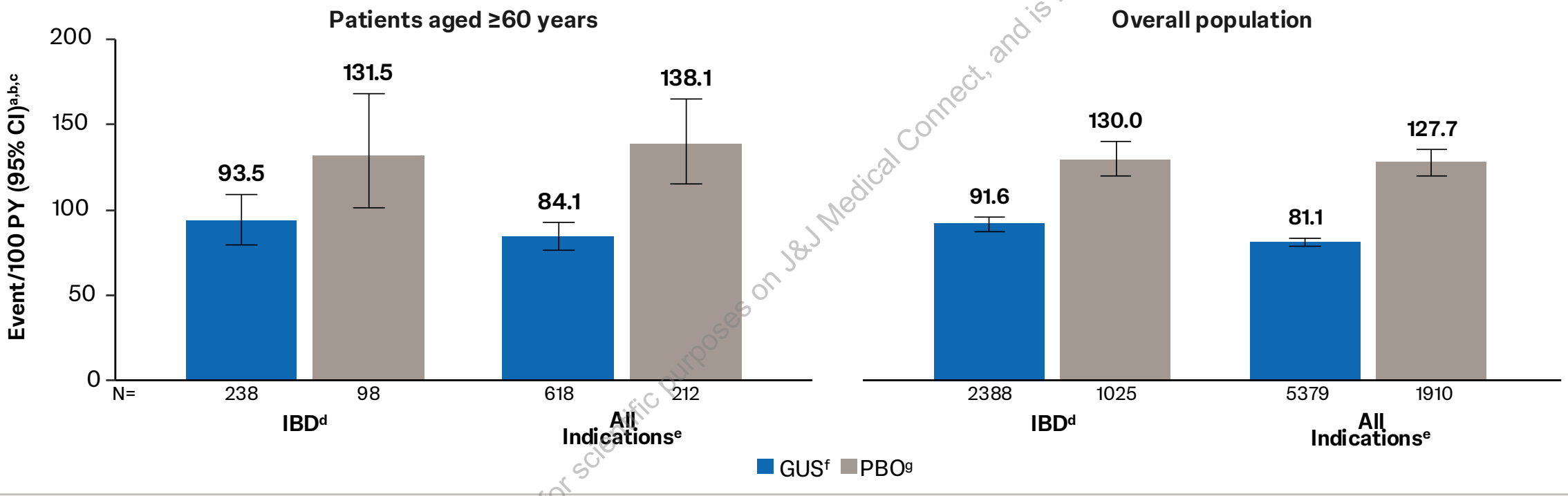
Exposure and Follow-up

Exposure and Follow-up Metrics by Age Group and Indication[a]	Patients aged ≥60 years				Overall population			
	IBD[b]		All indications[c]		IBD[b]		All indications[c]	
	GUS[d] (N=238)	PBO[e] (N=98)	GUS[d] (N=618)	PBO[e] (N=212)	GUS[d] (N=2388)	PBO[e] (N=1025)	GUS[d] (N=5379)	PBO[e] (N=1910)
Mean follow-up, weeks[f]	38.5	25.5	41.9	22.3	41.3	25.6	42.8	22.9
Mean treatment, weeks	31.1	22.4	32.8	19.2	34.0	21.9	33.7	19.5
Total PY of follow-up	175.5	47.9	496.8	90.5	1889.0	502.5	4411.7	836.5

- **IBD**: 238 patients aged ≥60 years received GUS for 175.5 patient-years of follow-up
- **All indications**: 618 patients aged ≥60 years received GUS for 496.8 patient-years of follow-up

[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]Includes UC and CD phase 2/3 GUS RCTs. [c]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. [d]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [e]UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomized to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. [f]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PY**=patient-years, **RCT**=randomized-controlled trial, **SCS**=summary of clinical safety, **UC**=ulcerative colitis, **W**=week.

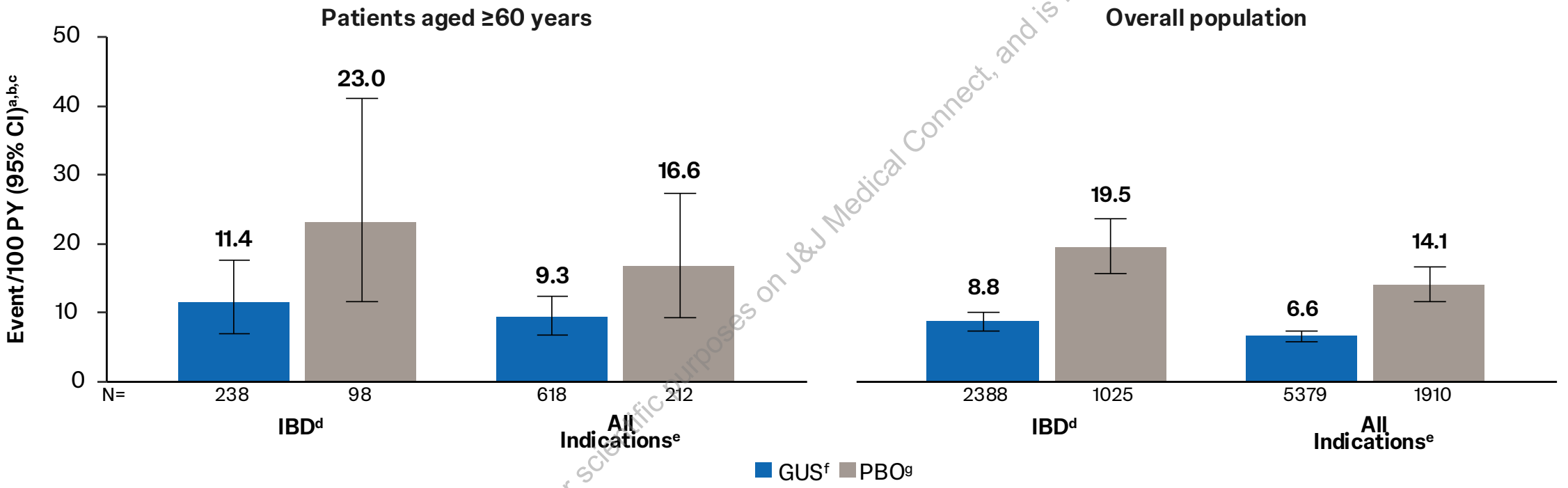
Exposure-Adjusted Incidence of Adverse Events



Adverse events were numerically lower with GUS vs PBO

[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution. [c]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [d]Includes UC and CD phase 2/3 GUS RCTs. [e]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. [f]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [g]UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomized to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PY**=patient-years, **RCT**=randomized-controlled trial, **SCS**=summary of clinical safety, **UC**=ulcerative colitis, **W**=week.

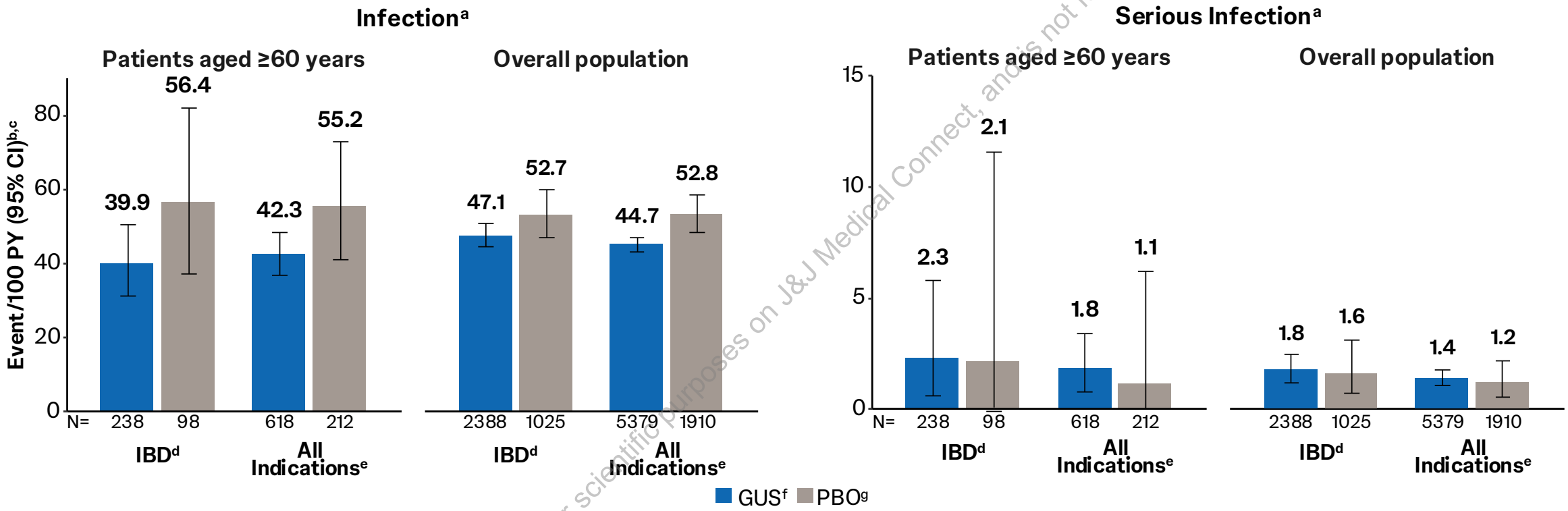
Exposure-Adjusted Incidence of Serious Adverse Events



- Serious adverse events were numerically lower with GUS vs PBO
- No deaths were reported with GUS across indications among patients aged ≥60 years

[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [c]Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution. [d]Includes UC and CD phase 2/3 GUS RCTs. [e]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. [f]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [g]UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomized to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PY**=patient-years, **RCT**=randomized-controlled trial, **SAE**=serious adverse event, **SCS**=summary of clinical safety, **UC**=ulcerative colitis, **W**=week.

Exposure-Adjusted Incidence of Infections and Serious Infections



- Infections were numerically lower with GUS vs PBO
- Rates of serious infections were comparable across treatment groups

[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [c]Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution. [d]Includes UC and CD phase 2/3 GUS RCTs. [e]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. [f]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [g]UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomized to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PY**=patient-years, **RCT**=randomized-controlled trial, **SAE**=serious adverse event, **SCS**=summary of clinical safety, **UC**=ulcerative colitis, **W**=week.

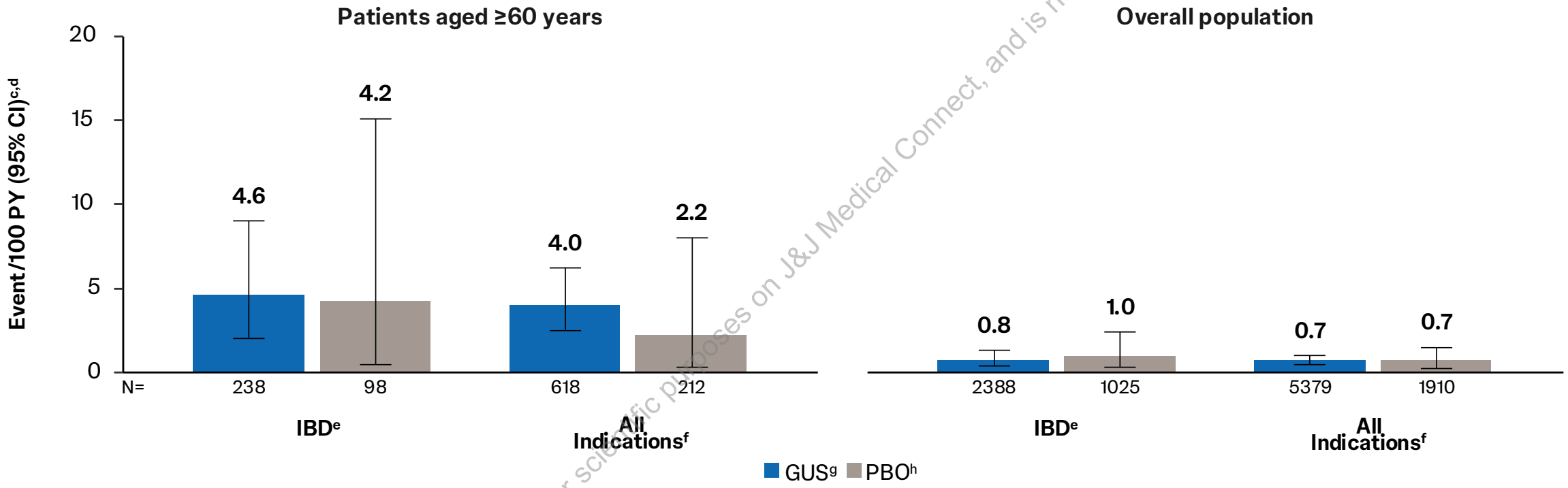
Exposure-Adjusted Incidence of Targeted Adverse Events

Targeted AEs by Age Group and Indication[a]	Patients aged ≥60 years				Overall population			
	IBD[b]		All indications[c]		IBD[b]		All indications[c]	
	GUS[d] (N=238)	PBO[e] (N=98)	GUS[d] (N=618)	PBO[e] (N=212)	GUS[d] (N=2388)	PBO[e] (N=1025)	GUS[d] (N=5379)	PBO[e] (N=1910)
Event/100 PY (95% CI)[f]								
Active tuberculosis[g]	0.0 (0.0, 1.7)	0.0 (0.0, 6.2)	0.0 (0.0, 0.6)	0.0 (0.0, 3.3)	0.1 (0.0, 0.3)	0.0 (0.0, 0.6)	<0.1 (0.0, 0.1)	0.0 (0.0, 0.4)
Opportunistic infection[h]	1.1 (0.1, 4.1)	2.1 (<0.1, 11.6)	0.6 (0.1, 1.8)	1.1 (<0.1, 6.2)	0.3 (0.1, 0.6)	0.6 (0.1, 1.8)	0.2 (0.1, 0.3)	0.4 (0.1, 1.0)
MACE[i]	1.1 (0.1, 4.1)	4.2 (0.5, 15.1)	1.2 (0.4, 2.6)	2.2 (0.3, 8.0)	0.3 (0.1, 0.7)	0.4 (<0.1, 1.4)	0.4 (0.2, 0.6)	0.4 (0.1, 1.0)
VTE[j]	0.6 (<0.1, 3.2)	2.1 (0.1, 11.6)	0.4 (<0.1, 1.4)	1.1 (<0.1, 6.2)	0.4 (0.2, 0.8)	0.2 (<0.1, 1.1)	0.3 (0.2, 0.5)	0.1 (0.0, 0.7)

- Opportunistic infections, MACEs, and VTEs were numerically lower with GUS vs PBO
- No cases of active tuberculosis were reported with GUS across indications among patients aged ≥60 years

[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]Includes UC and CD phase 2/3 GUS RCTs. [c]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. [d]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [e]UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomized to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. [f]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [g]Active tuberculosis events are identified by the MedDRA HLT of 'Tuberculous infections' excluding the preferred term of 'Latent tuberculosis'. [h]Opportunistic infections are defined as the narrow terms in the MedDRA SMQ of 'Opportunistic Infections'. [i]MACE were identified by clinical review. [j]VTE terms are based on customised MedDRA query. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **MACE**=major adverse cardiovascular event, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PY**=patient-years, **RCT**=randomized-controlled trial, **SCS**=summary of clinical safety, **UC**=ulcerative colitis, **W**=week, **VTE**=venous thromboembolism.

Exposure-Adjusted Incidence of Malignancies[a,b]



Malignancy (including non-melanoma skin cancer) rates were comparable with GUS and PBO

[a]Malignancies are defined as the narrow terms in the MedDRA SMQ of 'Malignant Tumours'. [b]The majority of malignancies reported in patients aged ≥60 years were non-melanoma skin cancers, primarily basal cell carcinoma and squamous cell carcinoma. [c]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [d]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [e]Includes UC and CD phase 2/3 GUS RCTs. [f]Includes PsA, PsO, UC, and CD phase 2/3 GUS RCTs. [g]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [h]UC: Data to first GUS dose (PBO) or ≥12W after last induction (re-randomized to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. **CD**=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **PY**=patient-years, **RCT**=randomized-controlled trial, **SAE**=serious adverse event, **SCS**=summary of clinical safety, **SMQ**=standardized MedDRA queries, **UC**=ulcerative colitis, **W**=week.

Key Takeaways

Among adults aged ≥60 years with CD, UC, PsO or PsA pooled from 14 RCTs, exposure-adjusted adverse event rates were similar to or lower than those observed with PBO through up to 1 year of follow-up

- ✓ This result was observed for adverse events, serious adverse events, infections, MACEs, and VTEs in both the IBD and all indications groups
- ✓ No deaths or active tuberculosis cases were reported with GUS
- ✓ Findings in adults aged ≥60 years were generally consistent with those observed in the overall study population

Overall, GUS showed a favorable safety profile in adults aged ≥60 years

CD=Crohn's disease, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **MACE**=major adverse cardiovascular event, **PBO**=placebo, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **RCT**=randomized-controlled trial, **UC**=ulcerative colitis, **VTE**=venous thromboembolism.