LOW RISK OF SERIOUS INFECTIONS AND INFECTIONS OF INTEREST IN PSORIASIS PATIENTS TREATED WITH GUSELKUMAB FOR UP TO 5 YEARS IN VOYAGE 1&2 PHASE 3 TRIALS

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BACKGROUND/OBJECTIVE

- Treatment of psoriasis with immunomodulatory biologics may increase the risk for certain types of infections (eg, candidiasis, herpes zoster)[1-3]
- Guselkumab (GUS), a monoclonal antibody targeting the p19 subunit of interleukin-23, is approved for the treatment of moderate to severe psoriasis and active psoriatic arthritis
- VOYAGE 1 and 2 were randomized, double-blinded, placebo (PBO)- and active-comparator-controlled Phase 3 studies that demonstrated the long-term efficacy and safety of GUS in patients (pts) with moderate to severe psoriasis[4,5]
  - Infection rates were low and comparable across groups during the PBO- and active-comparator periods of these studies[4,5]
- This analysis examines the risk of specific infection-related adverse events (AEs) in pts treated with GUS for up to 5 years using pooled data from VOYAGE 1 and 2

METHODS

- In both studies:
  - Pts randomized to:
    - GUS 100 mg at Week (W)0, W4, then Q8W
    - PBO at W0, W4, and W12, followed by GUS 100 mg at W16 and W20, then Q8W
    - Adalimumab (ADA) 80 mg at W0, 40 mg at W1, then 40 mg Q2W through W47 (VOYAGE 1) or W23 (VOYAGE 2)
  - In VOYAGE 1, all pts entered an open-label GUS treatment period during W52-252
  - In VOYAGE 2, all pts entered a randomized withdrawal and GUS retreatment period from W28-72; pts entered an open-label GUS treatment period during W76-252
  - The last dose of GUS was administered at W252; safety was evaluated through W264
- Pooled safety data were analyzed in the GUS group (including W16 PBO crossover, N=1221), the ADA→GUS group (N=500), and the combined GUS group (GUS and ADA→GUS groups, N=1721)
- Infection-related outcomes of interest included cumulative rates per 100 pt-years (PY) of overall, serious, and opportunistic infections (including active tuberculosis), along with treatment-emergent AEs (TEAEs) of *Candida* and herpes zoster infections

CONCLUSIONS

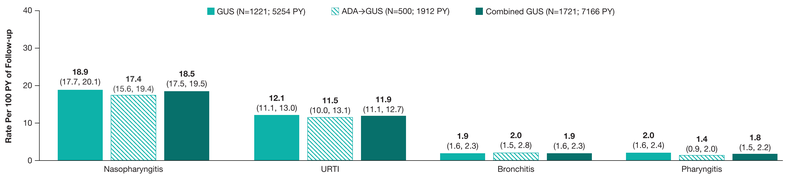
- **In 1721 pts with moderate to severe psoriasis who were treated with GUS for up to 5 years, observed infection-related AE patterns were consistent with previously reported shorter-term safety findings**
- **Serious infections and infection-related TEAEs of interest were infrequent**
- **These results support GUS as a generally well tolerated therapy for the long-term treatment of pts with moderate to severe plaque psoriasis**

RESULTS

Of 1721 pts treated with GUS, 78.4% (1349/1721) completed treatment with study drug through W252

- Total PY of follow-up: GUS (N=1221), 5254 PY; ADA→GUS (N=500), 1912 PY; Combined GUS (N=1721), 7166 PY

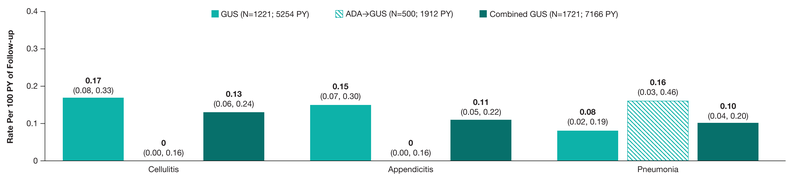
Across groups, the overall rate of infections ranged from 56.8 to 62.0 per 100 PY of follow-up. The most common (≥2.0 per 100 PY in any group) types of infections were nasopharyngitis, upper respiratory tract infection (URTI), bronchitis, and pharyngitis.



ADA, adalimumab; GUS, guselkumab; PY, patient-years; URTI, upper respiratory tract infection

Across groups, the overall rate of serious infections was low and ranged from 0.52 to 0.97 per 100 PY of follow-up. The most common (≥0.10 per 100 PY in any group) types of serious infections were cellulitis, appendicitis, and pneumonia.

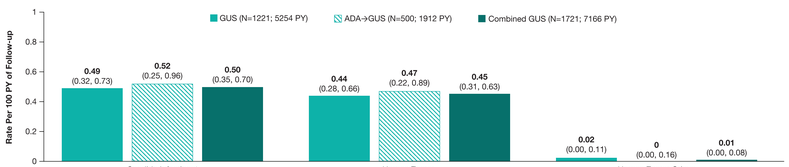
- In the combined GUS group, there were a total of 8 reported cases of cellulitis, 8 cases of appendicitis, and 7 cases of pneumonia in 7166 PY of follow-up



ADA, adalimumab; GUS, guselkumab; PY, patient-years

Incidence rates were low for TEAEs of interest, including *Candida* and herpes zoster infections

- No pt discontinued study drug due to an AE of *Candida* or herpes zoster infection
- All events resolved (some without treatment, some with standard topical or oral therapy)
- There were no reported opportunistic infections, including no cases of active tuberculosis, among GUS-treated pts from W0 to W264



*Search criterion: MedDRA high-level term, Candida infections
ADA, adalimumab; GUS, guselkumab; PY, patient-years

The most common *Candida* infections were vulvovaginal and skin infections

Rate (95% CI) per 100 PY of TEAEs of interest*	GUS (N=1221)	ADA→GUS (N=500)	Combined GUS (N=1721)
Overall *Candida* infections	0.49 (0.32, 0.73)	0.52 (0.25, 0.96)	0.50 (0.35, 0.70)
Vulvovaginal candidiasis	0.29 (0.16, 0.47)	0.05 (0.00, 0.29)	0.22 (0.13, 0.36)
Skin candida	0.11 (0.04, 0.25)	0.37 (0.15, 0.75)	0.18 (0.10, 0.31)
Oral candidiasis	0.04 (0.00, 0.14)	0.05 (0.00, 0.29)	0.04 (0.01, 0.12)
Genital candidiasis	0.02 (0.00, 0.11)	0.05 (0.00, 0.29)	0.03 (0.00, 0.10)
Balanitis candida	0.02 (0.00, 0.11)	0 (0.00, 0.16)	0.01 (0.00, 0.08)
Candida infection	0.02 (0.00, 0.11)	0 (0.00, 0.16)	0.01 (0.00, 0.08)

*Search criterion: MedDRA high-level term, Candida infections; preferred terms with rate >0 in any group are shown
ADA, adalimumab; CI, confidence interval; GUS, guselkumab; PY, patient-years; TEAEs, treatment-emergent adverse events

- Rates (95% CI) of non-pathogen-specific fungal infections suspicious for *Candida*† were as follows:
  - GUS (N=1221): 0.11 (0.04, 0.25)
  - ADA→GUS (N=500): 0.16 (0.03, 0.46)
  - Combined GUS (N=1721): 0.13 (0.06, 0.24)

†As determined by diagnosis and location; search criteria included MedDRA preferred terms of fungal balanitis, genital infection fungal, vulvovaginal mycotic infection, oral fungal infection, tongue fungal infection, oropharyngitis fungal, and fungal esophagitis. Only preferred terms matching these search criteria were included in this analysis.

Disclosures

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