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
- Gusekumab (GUS), a monoclonal antibody targeting the p19 subunit of interleukin-23, is approved for the treatment of moderate to severe psoriasis and active psoriatic arthropathies.

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. 1–3
- Infection rates were low and comparable across groups during the PBO- and GUS (N=1221) combined GUS (N=1721) group.

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 at W100 mg at W10 and W20, then Q8W
    - Adalimumab (ADA) 80 mg at W0, W4, and W8, then Q12W
  - Adalimumab (ADA) 80 mg at W0, W4, at W10, mg at W10, and Q12W QW47 (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 pts-years of overall, serious, and opportunistic infections (including active tuberculosis), along with treatment-emergent AEs (TEAEs) of Candida and herpes zoster infections.

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 serious infections was ranged from 0.52 to 0.97 per 100 PY of follow-up. The most common [0.10 per 100 PY in any group] 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

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

REFERENCES


**TABLES AND FIGURES**

- Table: Rates (% ) of non-pathogen-specific fungal infections suspicious for Candida
- Figure: Kaplan-Meier plots showing the incidence of infection-related adverse events in patients treated with GUS, ADA→GUS, and combined GUS groups

**DISCLOSURES**

- Employees of Janssen Research & Development, LLC: Served and has received compensation in the form of grant funding and/or honoraria as principal investigator for and is a paid consultant for Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and UCB.
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