Guselkumab is a fully human monoclonal antibody that binds and blocks 426 (86.2%) 14 (2.8%) Efficacy was assessed using prespecified analyses: non-responder imputation 10 (2.0%) 9 (1.8%) 4 (0.8%) 89.4 Adalimumab 3 (0.6%) 494 494 124 (25.1%) 21 (4.3%) 6 (1.2%) Guselkumab (Observed Data) Adalimumab PBO Treatment with guselkumab was well-tolerated 41.6 Guselkumab (NRI) Study results through up to 3 years of continuous treatment with guselkumab were examined.

Methods

In VOYAGE 1 (n=339), patients were randomized as follows (Figure 1): Guselkumab 200 mg administered by subcutaneous (SC) injection at Weeks 0, 4, and 12, then every 8 weeks (dMtx) Placebo (n=347) at Weeks 0, 4, and 12, followed by guselkumab 100 mg SC at Weeks 16 and 25, then 8 weeks (dMtx) – Additional 80 mg SC at Week 0, 40 mg of Week 1, then 42 mg SC/dMtx through Week 4 – Sterile at Week 12, all patients received open-label guselkumab 100 mg SC/dMtx through Week 155 Efficacy was assessed using prespecified analyses: non-responder imputation (NRI) through Week 48. Patients with missing efficacy data after application of treatment failure rules (TFR) were counted as non-responders, without regard to the reason for missing data and TFR starting at Week 52. Patients were considered non-responders after discontinuing due to lack of efficacy or worsening of psoriasis, or after use of a prohibited treatment.

Data for patients randomized to guselkumab and those originally randomized to placebo and then crossed over to guselkumab at Week 16 were combined (open-label group).

Conclusions

- High levels of response were maintained through up to 3 years of continuous guselkumab treatment in patients with moderate to severe plaque psoriasis, regardless of the data handling rules utilized.
- Treatment with guselkumab was well-tolerated.

Reference


This poster was supported by Janssen Research & Development, LLC.