15277

Malignancy rates and comparisons to the general US population through 3 years of follow-up in guselkumab-treated patients with moderate to severe psoriasis from the VOYAGE 1 and 2 trials

Kim A. Papp, K. Papp Clinical Research and Probity Research; Kristian Reich, MD, PhD, Center for Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, and Skinflammation Center Hamburg, Germany; Ken B. Gordon, Alexa B. Kimball, MD, MPH, Harvard Medical School; Paraneedharan Ramachandran, MD, Janssen R&D; Andrew Blauvelt, MD, MBA, Oregon Medical Research Center; Mark Lebwohl, Michael Song, Paraneedharan Ramachandran, Bruce Randazzo, Yaung-Kaung Shen

Objective: To summarize the incidence of malignancies by nonmelanoma skin cancer (NMSC) and malignancies other than NMSC or cervical cancer in situ, using pooled data from VOYAGE 1 and 2 through 3 years of guselkumab (GUS) treatment and to compare to expected rates in the general US population.

Methods: Rates of malignancies were evaluated cumulatively through 3 years in three groups: GUS (GUS, PBO→GUS), Adalimumab (ADA)→GUS, and ADA. Cumulative rates per 100 patient-years (PY) of follow-up, and by year of exposure through year 1, from year 1-2, and from year 2-3 were evaluated for GUS. The standardized incidence ratios (SIR; 95% CI) of malignancies other than NMSC or cervical cancer in situ reported in GUS-treated patients were compared with rates expected in the general US population derived from the NIH SEER database (2000-2015).

Results: A total of 1721 patients were treated with GUS (4153 PY of follow-up) through 3 years; 14 had NMSC and 19 had a malignancy other than NMSC. Rates per 100 PY (95% CIs) of NMSC were: GUS 0.28 (0.13-0.53); ADA→GUS 0.50 (0.16-1.17); and ADA 0.40 (0.05-1.44). Rates for other malignancies were: GUS 0.47 (0.26-0.77); ADA→GUS 0.40 (0.11-1.02); and ADA 0.40 (0.05-1.44). Analyses by year suggested no increase in rates of malignancy with longer duration of GUS exposure. Risk of malignancies through 3 years of GUS exposure was not increased compared with the general US population (combined GUS group SIR [95% CI]: 0.97 [0.58-1.52]). For malignancies occurring in ≥4 GUS-treated patients, SIRs (95% CIs) were: 1.73 (0.47-4.42) for breast cancer and 1.07 (0.29-2.73) for prostate cancer.

Conclusions: Through 3 years of GUS treatment in VOYAGE 1 and 2, overall incidence rates of malignancy were low and consistent with those expected in the general US population.

Commercial disclosure: This study was sponsored by Janssen Research & Development.

15280

Characterization of super responders to guselkumab treatment in moderate to severe psoriasis: Results from the VOYAGE 1 and 2 clinical trials

Kristian Reich, Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, and Skinflammation Center, Hamburg, Germany; Bruce Strober, MD, PhD, Yale University, New Haven, Connecticut, and Central Connecticut Dermatology Research, Cromwell; Richard Langley, Dalhousie University; Michael Song, Yaung-Kaung Shen, Yin You, MS, Janssen Research & Development; Peter Foley, MBBS, BMedSc, MD, FACD, University of Melbourne, St Vincent's Hospital Melbourne, Probity Medical Research, and Skin and Cancer Foundation, Melbourne, Victoria, Australia; Andrew Blauvelt, MD, MBA, Oregon Medical Research Center

Background: Guselkumab (GUS) is effective in treating moderate to severe psoriasis. Here, we characterized the baseline profile of patients with moderate to severe psoriasis achieving superresponse (defined as patients who achieved a Psoriasis Severity and Area Index [PASI] 100 response at both weeks 20 and 28) with GUS treatment.

Methods: Pooled data from the VOYAGE 1 and 2 trials were analyzed to identify superresponders and compare their baseline demographic and disease characteristics with patients who did not achieve a superresponse.

Results: In VOYAGE 1 and 2 (n = 1829), a subset of patients randomized to GUS were included in this analysis (n = 664). Through week 28, 271 GUS-treated patients were identified as superresponders. Compared with 393 GUS-treated patients who did not achieve a PASI 100 response at either week 20 or 28, superresponders were lighter (median weight ≤90 kg [62.4% vs 51.4%]), less obese (body mass index ≥30 kg/m^2 [35.4% vs 45.3%]), had less severe baseline disease (Investigator's Global Assessment score of 4 [16.2% vs 26.5%]), and had less previous use of systemic nonbiologic treatments (60.9% vs 69.0%). A greater proportion of superresponders achieved PASI 75 (week 4: 36.9% vs 16.0) and PASI 100 (week 8: 22.5% vs 3.3%) compared with patients who did not achieve a PASI 100 at either week 20 or 28. No other notable differences in relevant medical history were observed.

Conclusions: Superresponders among GUS-treated patients have distinct baseline demographic and disease characteristics and are more likely to achieve marked early clinical responses.

Commercial disclosure: This study was sponsored by Janssen Research & Development.

15281

Effects of guselkumab on articular components of American College of Rheumatology score and skin responses in patients with active psoriatic arthritis: Results from the phase 3 DISCOVER-2 study

Alice B. Gottlieb, MD, PhD, Icahn School of Medicine at Mount Sinai; Philip J. Mease, Joseph F. Merola, MD MMSc, Harvard Medical School, Brigham and Women's Hospital; Alexa P. Kollmeier, Elizabeth C. Hsia, Xie L. Xu, PhD, Janssen Research & Development; Prasheen Agarwal, Désirée van der Heijde, Iain B. McInnes and Wolf-Henning Boehncke

Objective: To evaluate guselkumab (GUS) for the treatment of PsA.

Methods: In DISCOVER-2, biologic-naïve patients (n = 739) with active PsA were randomized 1:1:1 to GUS 100 mg q4w; GUS 100 mg at wk 0, wk 4, then q8w; or placebo. The primary end point was wk 24 ACR20 response. Secondary analyses were performed for 7 American College of Rheumatology (ACR) components: swollen/tender joint count (SJC/TJC), patient pain assessment (0-10 cm VAS), patient and physician global assessments of disease activity (PtGA and PGA, respectively; 0-10 cm VAS), Health Assessment Questionnaire−Disability Index (HAQ-DI) scores (0-3), and C-reactive protein (CRP). PASI100, and Investigator's Global Assessment (IGA) 0 (cleared) responses are reported for patients with ≥3% psoriasis body surface area (BSA) and IGA ≥2 at baseline.

Results: At baseline mean (SD) HAQ-DI = 1.28 (0.58), BSA = 17.4% (20.4), and PASI = 9.9 (11.1); median SJC/TJC = 10/18 and CRP = 1.20 mg/dL; 8.7% of patients had IGA = 4 (severe). For the placebo, GUS q8w, and GUS q4w groups, respectively, wk-24 ACR20 response was 32.9%, 64.1%, and 63.7% (nominal $P < .001$, GUS vs placebo). Mean (SD) changes (baseline to wk 24) for ACR components were, respectively: SJC: −6.4 (7.2), −8.1 (6.1), −8.8 (5.5); TJC: −7.3 (11.2), −10.4 (9.5), −11.8 (9.9); patient pain assessment: −1.1 (2.4), −2.5 (2.5), −2.4 (2.4); PtGA: −1.2 (2.6), −2.5 (2.5), −2.4 (2.4); PGA: −2.5 (2.3), −3.8 (2.3), −3.9 (2.2); HAQ-DI: −0.16 (0.53), −0.40 (0.54), −0.43 (0.50); CRP (mg/dL): −0.54 (2.55), −1.08 (2.20), −1.04 (2.11). At wk 24, PASI100 was achieved by 2.7%, 45.5%, and 44.6% (nominal $P <$ .001, GUS vs placebo); IGA 0 was achieved by 7.7%, 50.0%, and 50.5% of patients, respectively (nominal $P < .001$, GUS vs placebo).

Conclusions: Across all ACR components of PsA activity, GUS provided greater improvements than placebo at wk 24, and half of the patients evaluated achieved clear skin.

Commercial disclosure: Janssen Research & Development.

15282

Electronic health record implementation associated with more timely communication of biopsy results

Efe Kakpovbia, BA, NYU School of Medicine; Arielle R. Nagler

Through the growing use of electronic health records (EHRs), physicians have adapted their method of communicating test results with patients. However, EHR use has also been associated with decreased physician productivity and impaired doctor-patient relationships. This retrospective study examined the impact of EHR implementation on the workflow surrounding patient notification of biopsy results at New York University Dermatologic Associates Faculty Group Practice, an outpatient dermatology practice in an academic institution. A total of 500 charts were randomly selected and included in this study. The mean time from pathology report finalization to patient notification of biopsy results before and after EHR implementation was 4.4 and 2.5 days, respectively ($P < .009$). The physician was more likely to notify the patient of benign results after EHR implementation (OR 10.07, 95% CI 6.04-16.90, $P < .001$). Fewer patients were notified by telephone for a benign diagnosis after EHR implementation, however most patients were notified by telephone for malignant diagnoses in both groups. The numbers of attempts made to notify the patient of their results before and after EHR implementation were 1.13 and 1.22, respectively ($P = .033$). There was no difference in time between biopsy procedure and definitive treatment of malignant lesions between groups. Despite the many drawbacks of EHR use, our study highlights how EHRs can improve patient care by decreasing time to patient notification of biopsy results. As providing high-quality, patient-centered care is an integral aspect of medical care, the use of EHRs among dermatologists should be encouraged.

Commercial disclosure: None identified.