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Frequency of gastrointestinal-related serious adverse events among guselkumab-treated patients with moderate to severe psoriasis: A pooled analysis of Voyage 1 and Voyage 2 through 3 years

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Background and Objective: Some biologics used to treat psoriasis are associated with exacerbation or new onset of inflammatory bowel disease (IBD). Long-term safety data through 3 years of continuous guselkumab (GUS) treatment from pivotal phase 3 clinical trials in moderate to severe psoriasis were analyzed for the incidence of GI-related serious adverse events (SAEs).

Methods: Using pooled safety data from the VOYAGE 1 and 2 studies, SAEs related to GI disorders were identified using the Medical Dictionary for Regulatory Activities (MedDRA) classification. Patients with a previous history of IBD were not excluded from these studies. Incidence rates of GI SAEs were calculated as the number of patients experiencing an SAE per 100 patient-years (PY) of follow-up.

Results: A total of 1721 patients were treated with GUS (4224 PY of follow-up) through 3 years. The overall rate of GI-related SAEs was 0.43/100 PY (n = 18 patients). The most commonly reported GI-related SAE was hemorrhoids (0.07/100 PY [n = 3 patients]); gastritis, hernia (inguinal and umbilical), pancreatitis, and acute pancreatitis each occurred at a rate of 0.05/100 PY (n = 2 patients each). Abdominal hernia, colitis, duodenal ulcer, hemorrhoidal hemorrhage, and irritable bowel syndrome were each reported in 1 patient (0.02/100 PY). No cases of exacerbation or new onset of IBD (Crohns disease or ulcerative colitis) were reported.

Conclusions: Through 3 years of follow-up with guselkumab treatment in VOYAGE 1 and 2, GI-related SAE rates were low and no new safety concerns were identified. There were no cases of IBD reported.

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

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Use of preemptive treatment for epidermal growth factor receptor inhibitor–related skin toxicity: The Dana Farber Cancer Institute experience

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Many patients treated with epidermal growth factor receptor inhibitors (EGFRis) experience dermatologic toxicities affecting quality of life (QoL) and causing treatment interruptions. The Skin Toxicity Evaluation Protocol with Panitumumab (STEPP) trial found reduced skin toxicity incidence and QoL impairment with preemptive doxycycline, topical steroids, moisturizers, and sunscreen. This study examined use of preemptive treatment for EGFRi-related skin toxicities in patients treated with cetuximab at Dana Farber Cancer Institute in 2012 and 2017, 2 years after the STEPP protocol and three years following establishment of the Department of Dermatology's Program in Skin Toxicities for Anticancer Therapy. 118 and 90 patients were treated with cetuximab in 2012 and 2017, respectively. Primary tumor types were colorectal, head and neck, and cutaneous squamous cell carcinoma (57%, 36%, 7%, respectively, in 2012; 48%, 38%, 14%, respectively, in 2017). >65% of patients in both cohorts were stage IV. At initiation of cetuximab, 28/118 and 42/90 patients were treated preemptively for rash in 2012 and 2017, respectively (24% vs 47%, $P < .001$). From 2012 to 2017, preemptive tetracycline and topical steroid use increased (7% to 69% and 46% to 71%, respectively) and topical antibiotic use decreased (82% to 43%), consistent with improved understanding that EGFRi-related rash is an inflammatory process distinct from acne (all $P < .05$). <15% of patients in both cohorts experienced dose interruptions from dermatologic toxicities. These results illustrate the value that access to dermatologists and education initiatives add to oncology care through increasing awareness of and adherence to evidence-based protocols and recommendation of appropriate agents for skin toxicity prevention and management.

Commercial disclosure: None identified.

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Patient-reported outcomes with abrocitinib treatment in patients with moderate to severe atopic dermatitis: Results from a randomized, phase 3 clinical trial

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Introduction: Atopic dermatitis (AD) imparts substantial patient burden, including pruritus and decreased quality of life (QoL). Here, patient-reported outcomes (PROs) are reported for patients with moderate to severe AD treated with abrocitinib or placebo in JADE MONO-1.

Design: Randomized, placebo-controlled, phase 3 trial (NCT03349060; JADE MONO-1).

Methods: Patients ≥12 years with clinical diagnosis of AD were randomly assigned (2:2:1) to once-daily abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 12 weeks. PROs included Patient Global Assessment (PtGA), Patient-Oriented Eczema Measure (POEM; scale 0-28), Dermatology Life Quality Index (DLQI; scale 0-30; adults), and Children's DLQI (CDLQI; scale 0-30; adolescents).

Results: Overall, 154, 156, and 77 patients were treated with abrocitinib 200 mg, abrocitinib 100 mg, or placebo, including 33 (21.4%), 34 (21.8%), and 17 (22.1%) adolescents. At week 12, 36.0%, 21.1%, and 6.8% of patients in the 200-mg, 100-mg, and placebo groups achieved PtGA response ("clear" or "almost clear" with ≥2-grade improvement from baseline). Median (interquartile range [IQR]) POEM improvements from baseline to week 12 were greater for 200 mg (21.0 [16.0-24.0] to 7.0 [3.0-14.0]) and 100 mg (20.0 [15.0-26.0] to 12.0 [5.0-19.0]) versus placebo (21.0 [17.0-24.0] to 15.0 [12.0-23.0]). Median DLQI (IQR) improvements from baseline to week 12 were greater for 200 mg (14.0 [9.0-20.0] to 2.5 [1.0-6.0]) and 100 mg (14.0 [10.0-18.0] to 6.0 [2.0-10.0]) versus placebo (13.0 [10.0-16.0] to 9.0 [5.0-13.0]). Similar improvements were observed for CDLQI.

Conclusions: Patients with moderate to severe AD treated with abrocitinib reported greater improvements in PROs of symptoms (POEM, PtGA) and QoL ([C]DLQI) compared with placebo.

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52-week evaluation of the efficacy of dupilumab for moderate to severe atopic dermatitis in clinical practice: A Canadian multicenter retrospective study

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Our knowledge of dupilumab's long-term efficacy for treatment of moderate to severe atopic dermatitis is limited to one phase III clinical trial evaluating dupilumab's efficacy beyond 16 weeks. To assess dupilumab's long-term efficacy, a retrospective chart review was conducted of patients meeting inclusion criteria (IGA ≥3, ≥18 years of age, ≥52 weeks of dupilumab treatment or discontinued dupilumab between weeks 16-52 due to lack of efficacy or due to an AE) at two tertiary hospitals in Toronto, Canada. Primary efficacy end point was measured by the proportion of patients reaching IGA 0/1 at week 52. 28/52 patients (54%) met IGA 0/1 at week 52. Further analysis revealed that 19/30 (63%) of the patients who initially met IGA 0/1 at week 16 maintained IGA 0/1 at week 52, while 5/18 (28%) of the non-responders at week 16 met IGA 0/1 at week 52. Of the four patients excluded from this analysis due to missing efficacy information at week 16, all achieved IGA 0/1 at week 52. In alignment with the results from the CHRONOS study, our study showed efficacy was maintained in the long-term with 54% of patients achieving IGA 0/1 at week 52. While majority of patients who initially met IGA 0/1 maintained efficacy at week 52 (63%), a considerable proportion of initial non-responders reached IGA 0/1 at week 52 (28%). Although larger studies are required, there may be value in continuing therapy despite lack of success in the short-term. This is especially important with limited safe and effective long-term treatments available.

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