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Long-term efficacy and safety of continuous q12w risankizumab: Results from the open-label extension LIMMitless trial

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Introduction: Risankizumab, a humanized IgG1 monoclonal antibody, selectively inhibits interleukin-23 through p19 binding. Risankizumab demonstrated superior efficacy compared with adalimumab and ustekinumab out to weeks 44 and 52, respectively, in patients with moderate to severe plaque psoriasis. Here, we evaluated the long-term efficacy and safety of continuous risankizumab treatment using data from the ongoing phase 3, multicenter, international, and open-label extension trial, LIMMitless (NCT03047395).

Methods: This analysis included 897 patients enrolled in LIMMitless that, in their base studies, were initially randomized to 150 mg risankizumab. The base studies, UltIMMa-1/2, IMMvent, SustaIMM, and NCT03255382, enrolled adults with moderate to severe plaque psoriasis. Further inclusion criteria for LIMMitless required patients to complete their base study and be candidates for long-term risankizumab. In LIMMitless, all patients received open-label 150 mg risankizumab every 12 weeks. From an interim analysis after 136 total weeks of risankizumab treatment, efficacy was assessed for 90%/100% improvement in Psoriasis Area Severity Index (PASI) using as observed analyses. Safety was assessed for all patients.

Results: Among those patients who have reached 136 total weeks of risankizumab treatment, the proportion of patients who had PASI 90/100 response were 86.8% (506/583)/61.4% (358/583). With 2296.5 patient years of exposure, there was no disproportionate increase in adverse events (AEs) compared with rates reported in the base studies. Rates of serious AEs, AEs leading to discontinuation, and AEs of safety interest were low and remained stable; no active TB infections were reported.

Conclusions: Long-term risankizumab treatment demonstrated durability of efficacy and favorable tolerability as observed in the base studies.

Commercial disclosure: 100% sponsored by AbbVie.

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Ten-year interim results from the ESPRIT registry: Real-world safety, effectiveness, and patient-reported outcomes of adalimumab for moderate to severe psoriasis

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Introduction: ESPRIT is a 10-year international prospective observational registry evaluating safety and effectiveness of originator-adalimumab in adults with moderate to severe plaque psoriasis. This is an interim analysis over the registry's 10 years.

Methods: Enrolled patients have continued adalimumab from a current prescription, a previous study, or initiated adalimumab ≤4 weeks pre-registry.

Results: are reported for patients who received ≥1 adalimumab dose in the registry. Analysis data were collected 26 September 2008 through 30 November 2018.

Results: Of 6065 patients originally enrolled, 6014 were included in this analysis. Incidence rates (IRs, events/100 patient-years) for treatment-emergent adverse events were 22.5 overall: 4.7 serious events, 1.3 malignancies, 1.0 serious infections, <0.1 active TB, 0.2 events leading to death. Standardized mortality ratio was 0.42 (95% CI 0.32-0.54). Outcomes are reported as percentage of patients (n/N) at 12-month intervals from Month 12 to 120. Month-120 Ns are based on available data. Achievement of Physician's Global Assessment (PGA) clear or minimal: 57.0% (2629/4616), 58.7% (2373/4041), 59.2% (2094/3539), 62.7% (2037/3250), 62.1% (1866/3006), 64.1% (1720/2685), 65.6% (1328/2025), 67.0% (977/1458), 70.9% (411/580), and 61.5% (8/13), respectively. Achievement of Dermatology Life Quality Index (DLQI) clear or minimal: 47.9% (1359/2836), 50.7% (1194/2357), 51.1% (1022/1999), 51.5% (898/1744), 53.2% (806/1514), 56.3% (730/1296), 55.5% (480/865), 58.2% (294/505), 57.4% (117/204), and 63.6% (7/11), respectively.

Conclusions: Safety in this 10-year interim analysis was consistent with the known adalimumab safety profile; no new safety signals were observed. Serious infection and malignancy IRs, and PGA, DLQI outcomes remained stable. Observed treatment-emergent death rate was below expected in an age-/sex-/country-matched population.

Commercial disclosure: 100% sponsored by AbbVie; medical writing support was provided by AbbVie.

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Development and accuracy of an artificial intelligence algorithm for acne evaluation

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Introduction: Smartphone applications have been proposed as diagnostic self-monitoring tools for acne.

Objective: Develop an artificial intelligence algorithm (AIA) for acne severity assessment (GEA) and lesion identification which was evaluated compared with clinical diagnosis by dermatologists.

Methods: Algorithm development steps: 1) collection of 6504 acneic patient images (face, right and left profiles) using smartphones. 2) Clean, prepare and manipulate data: Three dermatologists assessed GEA for each patient on images. Intra- and interdermatologist reproducibility were checked. For each patient, GEA given by the majority was used to train the algorithm. Lesion identification (retentional, inflammatory, pigmented) was performed by a dermatologist on pictures using a tagging tool and these pictures were used to train the algorithm. 3) Train model: Algorithm learned and adjusted its accuracy for GEA and lesions identification on pictures. Results were submitted to dermatologist for correction. 4.) Test data: A clinical study was performed on 53 acneic patients in order to compare GEA grading and lesion identification performed by three dermatologists in face to face, on images and by the algorithm. 5) Improvement of algorithm: based on the results obtained in step 4, new versions were proposed and tested.

Results: After improvement, accuracy of GEA and precision, recall and F1 score (accuracy) for the three types of lesions were evaluated. 89% of accuracy was obtained for GEA and F1 scores were 84% for inflammatory lesions, 72% for pigmented lesions and 61% for retentional lesions.

Conclusions: AIA is a promising tool for pre-evaluation of acne severity and lesion identification.

Commercial disclosure: None identified.

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Cutaneous toxicities in combination immune checkpoint inhibitor therapy for metastatic melanoma: Impact on therapy course

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Side effects of immune checkpoint inhibitor (ICI) therapy for metastatic melanoma (MM) are primarily immune-related adverse events (irAEs). The irAEs from anti-CTLA4 and anti-PD1 agents commonly affect the skin, GI, liver, and endocrine systems; occurring with higher incidences in combination versus monotherapy. Cutaneous adverse events (CAEs) are the earliest and most frequent irAEs with incidence of 40%-50% in monotherapy. Our retrospective study evaluated 157 treatment regimens in 155 patients with MM who received at least one dose of ipilimumab with either nivolumab (146 regimens) or pembrolizumab (11 regimens). CAEs manifested with 82 (52.2%) regimens and included eczema, morbilliform eruption, vitiligo, and pruritis. Out of the 157 regimens evaluated, 97 (61.7%) had discontinuation of treatment prior to the maintenance (anti-PD1 only) phase. IrAEs accounted for 59 (60.8%) of these discontinuations; however, CAEs contributed to 4 (6.8%) of these. Nine (11.0%) additional regimens had delays in combination dosing due to CAEs. Of the 13 regimens impacted by CAEs, 7 required systemic steroids and 4 were managed by topical steroids combined with oral antihistamines. Our database includes a real-world population not limited to clinical trial patients showing an incidence of 52.2% for CAEs on combination therapy compared with 40%-50% reported in literature for monotherapy. CAEs, however, have low impact on therapy course and are low grade, with management limited to topical and/or oral treatment. Both physicians and patients can benefit from being aware of which side effects pose the most risk of negatively impacting the course of combination ICI therapy for metastatic melanoma.

Commercial disclosure: None identified.