SKIN MANIFESTATIONS OF INTERNAL DISEASE

EXPERIENCE IN PATIENTS WITH A HISTORY OF MALIGNANCY THROUGH 3 YEARS OF CONTINUOUS TREATMENT WITH GUSELKUMAB IN THE VOYAGE 1 AND 2 TRIALS

A Blauvelt [1] - Ka Papp [2] - V Ho [3] - K Ghoreschi [4] - Bs Kim [5] - Y-k Shen [6] - P Ramachandran [7] - M Song [7] - J Uy [8] - J Crowley [9]

Oregon Medical Research Center, Dermatology, Portland, United States [1] - K Papp Clinical Research And Probity Medical Research Inc, Dermatology, Waterloo, Canada [2] - University Of British Columbia, Dermatology And Skin Science, Vancouver, Canada [3] - University Medical Center, Dermatology, Tübingen, Germany [4] - Pusan National University Hospital, Dermatology, Busan, Republic Of Korea [5] - Janssen Research & Development, Llc, Clinical Biostatistics, Spring House, United States [6] - Janssen Research & Development, Llc, Immunology, Spring House, United States [7] - Janssen Scientific Affairs, Llc, Dermatology, Horsham, United States [8] - Bakersfield Dermatology And Skin Cancer Medical Group, Dermatology, Bakersfield, United States [9]

Introduction/Objective: Malignancy is a potential safety concern for all immunosuppressive biologics. VOYAGE 1 & 2 are randomized, double-blinded, placebo/active comparator-controlled trials of guselkumab (a monoclonal antibody targeting interleukin 23) in moderate-to-severe plaque psoriasis. Patients with a history of malignancy but no recurrence within 5 years could participate.

Materials/Methods: Patients were randomized to guselkumab 100mg at Weeks0, 4, then q8w; placebo at Weeks0, 4, and 12, then guselkumab at Weeks 16, 20, then q8w; or adalimumab 80mg at Week0, 40mg at Week1, then q2w. In VOYAGE 1, from Week52 all patients received guselkumab q8w. VOYAGE 2 incorporated a randomized withdrawal study design at Week 28; all pts received guselkumab from Week 76. Malignancies (excluding nonmelanoma skin cancers [NMSC]) were assessed through Week 156 in patients with a history of malignancy at baseline.

Results: Of 1826 patients in VOYAGE 1/2, malignancy at baseline (GUS: n=10, PBO: n=5, ADA: n=5), included kidney, prostate, lung, testicular, thyroid, cervical, rectal, colon, and breast cancers, melanoma, dermatofibrosarcoma, and lymphoma. Through Week 156, 2 of these pts reported malignancies. One guselkumab patient in VOYAGE 1 with a history of prostate cancer developed metastatic invasive papillary breast carcinoma at study-day 202 and discontinued treatment. One adalimumab patient in VOYAGE 2 with a history of squamous cell bronchial carcinoma who switched to open-label GUS had a recurrence with

metastases at study-day 753 and died. No other significant safety issues were reported in this group. Serious adverse events were reported in 4 patients and NMSC was reported in 2 patients.

Conclusions: Among 20 pts with a history of malignancy exposed to guselkumab through 3 years, there was 1 new primary and 1
recurrence confounded by ADA exposure. More patients and longer duration of follow-up are needed to better characterize malignancy risk for guselkumab in patients with a history of malignancy.