MOJALANZA IN PSORIASIS PATIENTS WITH A HISTORY OF MALIGNANCY: 5-YEAR SAFETY FROM VOYAGE 1&2

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BACKGROUND/OBJECTIVE
- Malignancy is a potential safety concern for all immunomodulatory biologics. Patients with a history of malignancy are often excluded from clinical trials, which limits the availability of safety data for biologics in this population.
- Guselkumab (GUS), an interleukin-23 (IL-23) p19 subunit inhibitor, is approved for the treatment of moderate-to-severe psoriasis and active psoriatic arthritis. 
- VOYAGE 1 and 2 were Phase 3 studies that demonstrated the long-term efficacy and safety of GUS in patients with moderate-to-severe psoriasis.
- These studies included a small number of patients with a history of malignancy, particularly non-melanoma skin cancer (NMSC).

METHODS
- A description analysis of SAEs of malignancies and other SAEs occurred in GUS-treated patients with a history of malignancy (excluding NMSC) at baseline.
- Exposure to GUS was calculated for those patients with a history of malignancy at baseline.
- Patients were diagnosed with a malignancy during the study if treated at least one cell (cancerous) was detected in the tumor.

RESULTS

Of these 18 patients, 3 experienced SAEs of malignancy while participating in VOYAGE 1 or 2 for up to 5 years.

Patient 1: SAE of Recurrent Bronchial Carcinoma
- Diagnosis on Day 1139: 2.7 cm subareolar right breast mass
- Diagnosis on Day 202: 2.7 cm subareolar right breast mass
- Gene mutation identification testing was negative
- Diagnosis on Day 1168: possible; Sebaceous carcinoma (Right eyelid)
- Diagnosis on Day 1139: Not related; Resolved
- Diagnosis on Day 211: Not related; Resolved
- Diagnosis on Day 1378: Not related; Resolved
- Diagnosis on Day 1201: Not related; Not resolved
- Diagnosis on Day 753: Stage IVB (cT4 N3 M1c)
- Diagnosis on Day 573: Sebaceous carcinoma (Right eyelid; Possible; Resolved)

Patient 2: SAE of Recurrent Bronchial Carcinoma
- Diagnosis on Day 1168: possible; Sebaceous carcinoma (Right eyelid)
- Diagnosis on Day 1139: Not related; Resolved
- Diagnosis on Day 211: Not related; Resolved
- Diagnosis on Day 1378: Not related; Resolved
- Diagnosis on Day 1201: Not related; Not resolved
- Diagnosis on Day 753: Stage IVB (cT4 N3 M1c)

Patient 3: SAE of Invasive Melanoma
- Diagnosis on Day 1139: Right forear invasive melanoma
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SAEs Other Than Malignancies
- Of 18 patients with a prior history of malignancy at baseline, 5 had SAEs other than malignancies.

CONCLUSIONS
- Among 18 patients with a history of malignancy who were exposed to GUS for up to 5 years there were:
- 2 new primary malignancies (papillary breast carcinoma and invasive melanoma)
- 1 recurrence of bronchial carcinoma confined by exposure to adalimumab
- This analysis did not identify any new safety concerns that would limit the long-term use of GUS in patients with a history of malignancy.
- More patients and longer duration follow-up are needed to better characterize the use of GUS in patients with a history of malignancy.