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### **Complete Response of a Patient with Advanced Cutaneous Squamous Cell Carcinoma after Vilobelimab Monotherapy**

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#### **Introduction & Objectives:**

Vilobelimab is a novel targeted complement split factor C5a antibody which was tested as monotherapy and in combination with pembrolizumab in patients with PD-1 or PD-L1-resistant/refractory locally advanced or metastatic cutaneous squamous cell carcinoma (cSCC) in an open-label phase II trial. Here, we present one patient with cSCC with a long-lasting complete response to vilobelimab monotherapy.

#### **Materials & Methods:**

In the monotherapy arm of the trial (NCT04812535), vilobelimab was given in a loading dose of 800 mg intravenously on days 1, 4, 8, and 15 of cycle 1, followed by 1600 mg on days 22 and 36 of cycle 1, and days 1, 15, and 29 of cycle 2 and all subsequent cycles. Patients were assessed for efficacy with best overall response rate as primary endpoint according to RECIST v1.1/iRECIST and for safety with frequency and severity of treatment-emergent adverse events (TEAEs) and serious adverse events per MedDRA v27.0 and NCI CTCAE v5.0. The response evaluation was based on tumor assessments, using adequate imaging techniques including standardized medical photography, CT or MRI. The best overall response assignment depended on the findings of both target and non-target lesions, appearance and size of new lesions, and clinical stability. A steering committee continuously monitored patient safety throughout the study.

#### **Results:**

A 79-year-old female patient with locally advanced cSCC, tumor stage T2N0M0 and prognostic stage group IV and pretreated with cemiplimab, was enrolled into the study on 30-May-2022 and received 46 infusions of vilobelimab monotherapy until cycle 15, day 1 (end-of-treatment visit: 12-Feb-2024). The primary cSCC on her scalp was excised in 2019 and, after relapse in Nov 2021, treated with cemiplimab 350 mg iv Q3W for 144 days until May 2022 resulting in progressive disease as best response outcome. Two target lesions for study evaluation at baseline were at her scalp parietal left and fronto-parietal. At cycle 2, the patient achieved stable disease, from C3 to C5 partial response (PR) with 0 mm total tumor area but undetermined scar tissue, and since C6, after biopsy confirmation, complete response (CR) until C12. In total, overall response (CR+PR) lasted until 20-Nov-2023 (day 512) for at least 418 days.

The patient experienced 5 TEAEs, which were contusion, scalp hematoma, urinary tract infection, and traumatic hematoma, graded as mild, and fall graded with moderate intensity. All TEAEs were not related to the study drug and resolved without sequelae.

#### **Conclusion:**

Vilobelimab showed promising efficacy with a 60-week overall response duration in an elderly patient with locally advanced, stage IV cSCC and a good safety profile.

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