TPS9606 **Poster Session**

Neoadjuvant cemiplimab in cutaneous basal cell carcinoma of the head and neck.

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Background: Surgical resection of locally advanced basal cell carcinoma of the head and neck (laBCCHN) is often not feasible due to tumor size and proximity to vital structures with risk of significant deformity. Prior data suggest that neoadjuvant therapy could have a major impact on preserving critical structures, especially in the head and neck. The PD-1 inhibitor cemiplimab (REGN2810) has shown significant response rates for metastatic BCC after progression or intolerance of Hedgehog inhibitor (HHI) therapy. However, cemiplimab has not been investigated in the neoadjuvant setting for laBCCHN. To address this gap, this multi-center phase II study seeks to assess the response to neoadjuvant cemiplimab in the treatment of HHI-naïve laBCCHN. **Methods:** Patients with HHI-naive laBCCHN will receive response-adaptive, neoadjuvant IV cemiplimab 350mg every 3 weeks for an initial 2 cycles. The primary endpoint is the fraction of patients demonstrating clinical response after 2 cycles. All patients will undergo RECIST v1.1 response assessment by CT or MRI, and if not radiographically measurable, caliper measurement will be utilized to evaluate the primary endpoint. Those with RECIST v1.1 progression or stable disease with >5% growth will be considered non-responders and will proceed with surgery or other standard of care (e.g. HHI). Patients with stable disease (+5% to -20%) and RECIST v1.1 response will be considered responders and will continue to additional cycles of therapy and clinical assessment (imaging every 2 cycles, total cycles = 6). Patients with complete clinical response prior to completing 6 cycles may proceed to surgery for resection or biopsy of tumor site. Secondary endpoints include rate of functional organ preservation, pathologic response, safety, and quality of life. Correlative analyses will be performed on pre- and post-cemiplimab tumor specimens and peripheral blood samples to assess treatment-related changes in the immune microenvironment related to functional changes in immune cell composition. This study is open with 22 patients enrolled at the time of submission, with a planned total enrollment of 35 patients. Clinical trial information: NCT05929664. Research Sponsor: Regeneron Inc.