TPS9612 **Poster Session**

Trial in progress: A phase 3 randomized study of low-dose intralesional cemiplimab versus primary surgery for patients with early-stage cutaneous squamous cell carcinoma (CLEAR CSCC).

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Background: Cemiplimab 350 mg administered intravenously every 3 weeks is approved for the treatment of advanced cutaneous squamous cell carcinoma (CSCC). Surgery is the standard of care for early-stage CSCC; however, for patients who prefer non-surgical management of early-stage CSCC, low-dose intralesional (IL) cemiplimab has demonstrated promising clinical activity in a pilot study (NCT03889912). The purpose of this study (NCT06585410) was to determine the non-inferiority of IL cemiplimab versus primary surgery, along with its safety, tolerability, and efficacy in patients with early-stage CSCC. **Methods:** In this phase 3, randomized, open-label, multicenter study, approximately 369 patients with early-stage CSCC will be randomized 2:1 to cemiplimab (5 mg IL every week for 6 weeks) versus primary surgery. Key inclusion criteria include: patients aged ≥18 years; a histologically confirmed invasive CSCC target lesion that is ≥1.0–≤2.0 cm (longest diameter) located in the head and neck, hand, or pre-tibial surface; adequate performance status; and adequate hepatic, renal, and bone marrow function. Key exclusion criteria include target lesion of keratoacanthoma, autoimmune disease requiring treatment with systemic autoimmune suppressants, concurrent or prior solid tumor or hematologic malignancy (except for protocol-allowed exceptions), and a history of solid organ transplant. Patients will be followed for approximately 3 years. The primary objective is to assess the non-inferiority of IL cemiplimab versus primary surgery by event-free survival. Secondary objectives include safety, tolerability, longest diameter of surgical defect after resection in both arms, and composite complete response in the experimental arm. Study recruitment is planned to start in 2025. Enrollment is planned at study sites across North America, Australia, and Europe. Clinical trial information: NCT06585410. Research Sponsor: Regeneron Pharmaceuticals, Inc.