1122TiP Pembrolizumab in patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC): The phase II KEYNOTE-629 study

L.F. Licitra[1], L.L. Siu[2], E.E.W. Cohen[3], P. Zhang[4], B. Gumuscu[4], R. Swaby[4], K. Harrington[5]

[1]Head and Neck Medical Oncology Unit, Fondazione IRCCS Istituto Nazionale dei Tumori, University of Milan, Milan, Italy, [2]Medical Oncology and Hematology, Princess Margaret Cancer Centre, Toronto, ON, Canada, [3]Department of Translational Science, University of California San Diego Health, Moores Cancer Center, La Jolla, CA, USA, [4]Medical Oncology, Merck & Co, Inc, Kenilworth, NJ, USA, [5]Head and Neck/Skin Units, The Institute of Cancer Research, London, UK

Background: There are no approved treatments or standard of care for recurrent or metastatic cSCC. Effectiveness of common therapies for cSCC is limited. Regimens effective for SCC of the head and neck (HNSCC) may also be effective for cSCC. Pembrolizumab is a programmed death 1 (PD-1) inhibitor that directly blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2. Evidence of pembrolizumab efficacy and safety has been shown in patients with recurrent or metastatic HNSCC in the phase 1b KEYNOTE-012 study. The single-arm, open-label phase 2 KEYNOTE-629 trial will be conducted to evaluate the efficacy and tolerability of pembrolizumab in patients with previously treated recurrent or metastatic cSCC (NCT03284424).

Trial design: Patients will be given pembrolizumab 200 mg every 3 weeks by intravenous infusion, continued for 35 doses (~2 years) or until disease progression, unacceptable toxicity, intercurrent illness, nonadherence, or investigator or patient decision to withdraw. Radiographic imaging will be performed every 6 weeks for year 1 and every 9 weeks thereafter. Adverse events will be monitored and graded per National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.0. Key inclusion criteria are age $\geq$18 years; histologically confirmed cSCC as the primary site of malignancy; metastatic disease or locally recurrent disease not curable by surgery or radiation; measurable disease per RECIST v1.1; and Eastern Cooperative Oncology Group performance status 0/1. There is no requirement for prior chemotherapy or biological systemic treatment for incurably recurrent/metastatic disease. Primary end point is objective response rate per RECIST v1.1 assessed by blinded independent central review. Secondary end points are duration of response, disease control rate (complete or partial response or stable disease for $\geq$12 weeks), progression-free survival per RECIST v1.1, overall survival, safety, and tolerability. Pharmacokinetics, biomarkers, and health-related quality of life will be evaluated as exploratory end points. Recruitment is ongoing in 10 countries and will continue until 100 patients are enrolled.

Clinical trial identification: NCT03284424. Trial initiated September 15, 2017.

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