toxicity, or patient/physician decision to withdraw. Patients will be evaluated to determine necessity of neck dissection 12 weeks after completion of CRT. Primary end point is event-free survival and secondary end points are overall survival, safety, and patient-reported outcomes. Biomarkers will be an exploratory end point. Recruitment is ongoing in 21 countries and will continue until ~780 patients are enrolled.

Clinical trial identification: NCT03040999, trial initiation date: 2/2/17.

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1121TiP KEYNOTE-412: Phase III study of pembrolizumab plus chemoradiation vs chemoradiation alone for locally advanced head and neck squamous cell carcinoma (HNSCC)

J-P. Machiels[1], L. Licitra[2], Y.G. Tao[3], C-J. Yen[4], D. Rischin[5], J.N. Waldron[6], B.A. Burtness[7], V. Gregoire[1], S.S. Agarwala[8], J. Yorio[9], J-P. Delord[10], S. Aksoy[11], S. Ikeda[12], R-L. Hong[13], J.Y. Ge[14], H. Brown[14], B. Bidadi[14], L.L. Siu[6]

[1]Oncology, Cliniques Universitaires Saint-Luc, Brussels, Belgium, [2]Oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, University of Milan, Milan, Italy, [3]Oncology, Gustave Roussy, Villejuif, France, [4]Internal Medicine, National Cheng Kung University Hospital, Tainan, Taiwan, [5]Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia, [6]Medical Oncology and Hematology, UHN Princess Margaret Cancer Centre, Toronto, ON, Canada, [7]Medicine, Yale University School of Medicine, New Haven, CT, USA, [8]Oncology, St. Luke's Cancer Center, Bethlehem, PA, USA, [9]Oncology, Texas Oncology–Austin Central, Austin, TX, USA, [10]Oncology, Institut Claudius Régaud, Toulouse, France, [11]Oncology, Hacettepe University, Ankara, Turkey, [12]Oncology, Medical Hospital, Tokyo Medical and Dental University, Tokyo, Japan, [13]Oncology, National Taiwan University Hospital, Taipei, Taiwan, [14]Medical Oncology, Merck & Co, Inc, Kenilworth, NJ, USA

Background: Preclinical data suggest improved tumor growth control and survival when radiation therapy (RT) is combined with a PD-1 inhibitor. Pembrolizumab is effective for treatment of recurrent/metastatic HNSCC, and initial results from a phase 1b study suggest that pembrolizumab plus chemoradiation therapy (CRT) is tolerable in patients with locally advanced (LA) HNSCC. KEYNOTE-412 (NCT03040999) is a phase 3, randomized, placebo-controlled, double-blind trial to determine efficacy and safety of pembrolizumab plus CRT and as maintenance therapy vs placebo plus CRT in LA-HNSCC.

Trial design: Eligibility criteria are age ≥18 years; newly diagnosed, treatment-naive, oropharyngeal p16–positive (any T4 or N3), oropharyngeal p16–negative (any T3-T4 or N2a-N3), or larynx/hypopharynx/oral cavity (any T3-T4 or N2a-N3) SCC; evaluable tumor burden (RECIST v1.1); and ECOG performance status 0/1. Patients will be randomly assigned (1:1) to receive pembrolizumab 200 mg every 3 weeks plus cisplatin-based CRT or placebo plus cisplatin-based CRT. Treatment will be stratified by RT regimen (accelerated RT [56-70 Gy, 6 fractions/week for 6 weeks] or standard RT [56-70 Gy, 5 fractions/week for 7 weeks]), tumor site/p16 status (oropharynx p16 positive vs p16 negative or larynx/hypopharynx/oral cavity), and disease stage (III vs IV). Priming dose of pembrolizumab or placebo will be given 1 week before CRT, followed by 2 doses during CRT, and an additional 14 doses after CRT, for a total of 17 pembrolizumab or placebo infusions. Response will be assessed by MRI and CT 12 weeks after CRT, every 3 months for 3 years, then every 6 months for years 4 and 5. Treatment will be discontinued at time of centrally confirmed disease progression, unacceptable