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1752P Post hoc analysis of pembrolizumab efficacy in potentially platinum ineligible patients with urothelial carcinoma enrolled in KEYNOTE-052 and LEAP-011

Y. Loriot[1], T. Csoszi[2], N. Matsubara[3], S.J. Shin[4], S.H. Park[5], V. Atduev[6], M. Gumus[7], B.B. Karaca[8], P. Grivas[9], R. De Wit[10], A.O. Siefker-Radtke[11], D.E. Castellano Gauna[12], P.H. O'Donnell[13], T.B. Powles[14], J. Vuky[15], Y. Zhao[16], K. O'hara[17], S. Franco[16], B. Homet Moreno[18], J. Zolnierek[19]

[1]Cancer Medicine, Gustave Roussy, Université Paris-Saclay, Villejuif, France; [2]Medical Oncology, Jász-Nagykun-Szolnok County Hospital, Szolnok, Hungary; [3]Medical Oncology, National Cancer Center Hospital East, Chiba, Japan; [4]Internal Medicine, Severance Hospital, Seoul, Republic of Korea; [5]Medicine, Samsung Medical Center, Seoul, Republic of Korea; [6]Faculty Surgery and Transplantology, Volga District Medical Center, Federal Medical-Biological Agency, Nizhny Novgorod, Russian Federation; [7]Medical Oncology, Istanbul Medeniyet University, Istanbul, Turkey; [8]Medical Oncology, Tulay Aktas Onkoloji Hastanesi, Izmir Bornova, Turkey; [9]Medical Oncology, University of Washington and Fred Hutchinson Cancer Center, Seattle, WA, USA; [10]Medical Oncology, Erasmus MC Cancer Institute, Rotterdam, Netherlands; [11]Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [12]Medical Oncology, Hospital Universitario 12 de Octubre, Madrid, Spain; [13]Hematology and Oncology, The University of Chicago, Chicago, IL, USA; [14]Centre of Experimental Cancer Medicine, Barts Cancer Institute, Queen Mary University of London, London, UK; [15]Division of Hematology & Medical Oncology, Oregon Health & Science University, Knight Cancer Institute, Portland, OR, USA; [16]Medical Oncology, Merck & Co., Inc., Rahway, NJ, USA; [17]Research and Development, Eisai Inc., Nutley, NJ, USA; [18]Clinical Research, Merck & Co., Inc., Rahway, NJ, USA; [19]Oncology, LUXMED Oncology, Warsaw, Poland

Background: First-line pembrolizumab monotherapy is a standard of care option in platinum-ineligible patients with advanced UC in the US. However, there is no standard definition of platinum ineligibility; treatment decisions are based on clinical judgment. It is of interest to determine whether efficacy of pembro in UC varies based on criteria used to define platinum ineligibility.

Methods: This post hoc analysis pooled pts treated with pembro monotherapy from KEYNOTE-052 (N=370; NCT02335424) and LEAP-011 (N=242; NCT03898180) who were potentially platinum ineligible based on criteria determined by an extensive search of the literature. Candidate criteria for platinum ineligibility identified in the literature included ECOG PS 2, renal dysfunction (GFR <60 mL/min), visceral disease, and age ≥80 y. Subgroups of pts with several combinations of these criteria were selected for this analysis: ECOG PS 2 (with or without age ≥80 y, renal dysfunction, or visceral disease); age ≥80 y with renal dysfunction; or visceral disease (with or without age ≥80 y or renal dysfunction). Efficacy end points were ORR and OS.

Results: The database cutoffs were September 26, 2020 (KEYNOTE-052), and July 26, 2021 (LEAP-011); median (range) follow-up was 56.3 mo (51.2-65.3) and 7.0 mo (0.2-25.0), respectively. In the primary analyses, ORR (95% CI) was 28.9% (24.3-33.8) in KEYNOTE-052 and 28.9% (23.3-35.1) in the pembro monotherapy arm of LEAP-011; median (95% CI) OS was 11.3 (9.7-13.1) and 12.9 (9.8-17.8) mo, respectively. ORR ranged from 23.5%-33.3%, and median OS ranged from 9.0-10.6 mo among the subgroups (Table).

Conclusions: In this post hoc exploratory analysis, responses to pembro monotherapy occurred regardless of the criteria used to define platinum ineligibility for pts with UC. Median OS was generally consistent among subgroups and was similar to the overall pt populations.

Clinical trial identification: KEYNOTE-052 (NCT02335424) and LEAP-011 (NCT03898180) Release date: KEYNOTE-052 (January 9, 2015); LEAP-011 (April 1, 2019).

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Matsubara: Financial Interests, Personal, Invited Speaker: National Cancer Center Hospital East; Financial Interests, Personal, Speaker's Bureau: National Cancer Center Hospital East; Financial Interests, Personal, Advisory Board: National Cancer Center Hospital East; Financial Interests, Institutional, Research Grant: National Cancer Center Hospital East; Financial Interests, Institutional, Funding: National Cancer Center Hospital East. M. Gumus: Financial Interests, Institutional, Research Grant: Istanbul Medeniyet University; Financial Interests, Institutional, Funding: Istanbul Medeniyet University; Financial Interests, Institutional, Principal Investigator: Istanbul Medeniyet University. B.B. Karaca: Financial Interests, Personal, Advisory Role: Bristol Myers Squibb, Novartis, MSD; Financial Interests, Personal, Funding: MSD, Novartis. P. Grivas: Financial Interests, Personal, Other, Consulting: AstraZeneca, Astellas Pharma, Bayer, Bristol Myers Squibb, Dyania Health, EMD Serono, Exelixis, Foundation Medicine, Genentech/Roche, Genzyme, GlaxoSmithKline, Guardant Health, Gilead Sciences, Infinity Pharmaceuticals, Janssen, Lucence Health, Merck, Mir; Financial Interests, Institutional, Research Grant: Bavarian Nordic, Bristol Myers Squibb, Clovis Oncology, Debiopharm, EMD Serono, G1 Therapeutics, Gilead Sciences, GlaxoSmithKline, Merck, Mirati Therapeutics, Pfizer, QED Therapeutics. R. De Wit: Financial Interests, Personal and Institutional, Invited Speaker: Sanofi; Financial Interests, Personal and Institutional, Research Grant: Sanofi, Bayer; Financial Interests, Personal, Advisory Board: Merck, Orion, Astellas; Financial Interests, Personal and Institutional, Advisory Board: Bayer; Financial Interests, Personal, Invited Speaker: Astellas. A.O. Siefker-Radtke: Financial Interests, Personal, Invited Speaker: Janssen; Financial Interests, Personal, Advisory Board: Astrazeneca, Basilea, Bristol Myers Squibb, Curio, Genentech, Gilead, Ideaya, Immunomedics, Janssen, Oncology, Merck Sharp & Dohme, Natera, Nektar Therapeutics, Taiho, Seagen; Financial Interests, Personal, Funding: Basilea, Bristol Myers-Squibb, Janssen, Merck Sharpe & Dohme, Nektar Therapeutics (Clinical Trial Support); Financial Interests, Personal, Other: Basilea, Bristol Myers-Squibb, Janssen, Merck Sharpe & Dohme, Nektar Therapeutics (Clinical Trial Support). D.E. Castellano Gauna: Financial Interests, Personal, Advisory Role: Janssen Oncology, Roche/Genentech, Astellas Pharma, AstraZeneca, Pfizer, Novartis, Ipsen, Bristol Myers Squibb, MSD Oncology, Bayer, Lilly, Sanofi, Pierre Fabre, Boehringer Ingelheim; Financial Interests, Institutional, Funding: Janssen Oncology; Financial Interests, Personal, Other, Travel, Accommodations, Expenses: Pfizer, Roche, Bristol Myers Squibb, AstraZeneca Spain. P.H. O'Donnell: Financial Interests, Personal, Other, Travel, Accommodations, Expenses: Seattle Genetics, Genentech/Roche, Janssen; Financial Interests, Personal, Other: Janssen, Nektar, NIH, Dragonfly Therapeutics, G1 Therapeutics; Financial Interests, Personal, Stocks/Shares: Allergan; Financial Interests, Personal, Other, Honoraria: Genentech/Roche; Merck; Astellas Pharma; Seattle Genetics; Atheneum; Health Advances; Janssen; Dedham Group; Pfizer; CLD, Inc.; Axiom Healthcare Strategies; EMD Serono; IntrinsiQ Specialty Solutions; ISMIE; NAMCP; Financial Interests, Institutional, Funding: Boehringer Ingelheim, Merck, Genentech/Roche, AstraZeneca/MedImmune, Acerta Pharma, Janssen, Seattle Genetics, Bristol Myers Squibb, Astellas Pharma. T.B. Powles: Financial Interests, Personal, Advisory Role: AstraZeneca, BMS, Exelixis, Incyte, Ipsen, Merck, MSD, Novartis, Pfizer, Seattle Genetics, Merck Serono, Astellas, Johnson & Johnson, Eisai, Roche, Mashup Ltd.; Financial Interests, Personal, Research Grant: AstraZeneca, BMS, Exelixis, Ipsen, Merck, MSD, Novartis, Pfizer, Seattle Genetics, Merck Serono, Astellas, Johnson & Johnson, Eisai, Roche; Financial Interests, Personal, Other, Travel/Accommodation/Expenses: Roche, Pfizer, MSD, AstraZeneca, Ipsen. J. Vuky: Financial Interests, Institutional, Sponsor/Funding: Agendia, Arvinas, Astellas Pharma, AstraZeneca, Blueprint Medicines, Bristol Myers Squibb, Celldex, Clovis Oncology, Deciphera, Eisai, Exelixis, Fortis, Roche/Genetech, Ignyta, Incyte, Innocrin Pharma, Lilly, Loxo, Merck, Novartis, Pfizer, Polyphor, Rgeni; Financial Interests, Personal, Advisory Board: Seattle Genetics/Astellas. Y. Zhao: Financial Interests, Personal, Full or part-time Employment: Merck & Co., Inc. K. O'hara: Financial Interests, Personal, Full or part-time Employment: Eisai. S. Franco: Financial Interests, Personal, Full or part-time Employment: Merck & Co., Inc.; Financial Interests, Personal, Stocks/Shares: Merck & Co., Inc. B. Homet Moreno: Financial Interests, Personal, Full or part-time Employment: Merck & Co., Inc.; Financial Interests, Personal, Stocks/Shares: Merck & Co., Inc. J. Zolnierek: Financial Interests, Personal, Invited Speaker: MSD; Financial Interests, Personal, Advisory Board: MSD. All other authors have declared no conflicts of interest.

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1753P Cost-effectiveness (CE) of nivolumab (NIVO) as adjuvant treatment of muscle invasive urothelial carcinoma at high risk of recurrence (MIUC-HR) in France

M.S. Negrier[1], F.P. Colrat[2], J. Bonastre[3], C. Chamielec[4], S. Teitsson[5], C. Knight[6], L. Ni[6], J. Chevalier[4], A-F. Gaudin[2], M. Roupret[7], S. Branchoux[2]

[1]Oncologie Médicale, Centre Leon Berard, Lyon, France; [2]Health economics and outcome research, Bristol Myers Squibb SARL, Rueil-Malmaison, France; [3]Biostatistics and Epidemiology, Institut Gustave Roussy, Villejuif, France; [4]Paris, Vyoo Agency, Paris, France; [5]Health economics and outcome research, Bristol Myers Squibb Pharmaceuticals Limited - Uxbridge, Uxbridge, UK; [6]Health economics, RTI Health Solutions, Manchester, UK; [7]Urologie, Sorbonne Université - Site Saint-Antoine, Paris, France

Background: NIVO is the first immuno-oncology drug to demonstrate significantly improved disease-free (DF) survival for the adjuvant treatment of patients (pts) with MIUC-HR who had undergone radical resection, compared to placebo (PBO). The objective of this study was to assess the CE of NIVO versus surveillance (SURV), a proxy of PBO, in this indication in France.

Methods: A 4-state (DF, local recurrence (LR), distant recurrence (DR), death) semi-Markov model was used to conduct an analysis from the French healthcare system

Table: 1752P

	Age ≥80 y + renal dysfunction n=111	ECOG PS 2 only n=355	ECOG PS 2 + age ≥80 y n=87	ECOG PS 2 + renal dysfunction n=176	ECOG PS 2 + visceral disease n=285	Visceral disease + age ≥80 y n=116	Visceral disease + renal dysfunction n=307
ORR, % (95% CI)	27.9 (19.8-37.2)	26.2 (21.7-31.1)	33.3 (23.6-44.3)	27.8 (21.4-35.1)	23.5 (18.7-28.9)	26.7 (18.9-35.7)	25.7 (20.9-31.0)
OS, median (95% CI), months	10.6 (6.8-12.3)	10.1 (8.6-11.7)	9.3 (6.3-12.2)	10.1 (8.6-13.8)	9.1 (7.2-10.8)	9.0 (6.1-11.3)	10.6 (9.0-12.5)
12-month OS, %	43.3	44.3	40.5	45.2	40.2	35.4	45.2