

Table A2. Independent Review Facility–Assessed Objective Response Rates (per Response Evaluation Criteria in Solid Tumors [RECIST] version 1.1) Versus Historical Data for All Subgroups

Line of Therapy (ordered by testing procedure)	PD-L1 Status*	No. of Treated Patients	Prespecified Historical Control Response Rate (%)†	ORR, % (95% CI)‡
≥ 3L	TC2/3 or IC2/3	253	5	17 (13 to 23)
≥ 3L	TC3 or IC2/3	236	5	18 (14 to 24)
≥ 3L (cohort 3)	TC3 or IC3	115	5	27 (19 to 36)
≥ 2L	TC2/3 or IC2/3	520	7	17 (14 to 21)
≥ 2L	TC3 or IC2/3	483	7	18 (15 to 22)
≥ 2L (cohorts 2/3)	TC3 or IC3	237	7	25 (20 to 31)
All lines (all three cohorts)	TC3 or IC3	302	15	26 (21 to 31)

NOTE: On the basis of a data cutoff of May 28, 2015. Data analysis was performed approximately 6 months after the last patient was enrolled. Objective response rates (ORRs) were 17% to 19% for patients with TC2/3 or IC2/3 tumors and 26% to 27% for the TC3 or IC3 subgroup. The median overall survival (95% CI) for patients with TC2/3 or IC2/3 tumors was 14.0 months (14.0 months to NE), NE (11.2 months to NE), and NE (8.4 months to NE) for cohorts 1, 2, and 3, respectively, with 6-month cumulative survival rates of 82%, 76%, and 71%, respectively. (The median survival was immature for the TC3 or IC3 subgroup.)

Abbreviations: 2L, second line; 3L, third line; IC, tumor-infiltrating immune cells; NE, not estimable; PD-L1, programmed death-ligand 1; TC, tumor cells; TC2/3 or IC2/3 = TC or IC ≥ 5% PD-L1-expressing cells, respectively; TC3 or IC3 = TC ≥ 50% or IC ≥ 10% PD-L1-expressing cells, respectively.

*PD-L1-expressing TC: TC3 = ≥ 50%; TC2 = ≥ 5% and < 50%. Percentage of PD-L1-expressing IC in tumor microenvironment: IC3 = ≥ 10%; IC2 = ≥ 5% and < 10%.

†Prespecified historical control response rates shown were solely on the basis of prior lines of chemotherapy received.

‡P < .001 for each ORR value compared with respective historical chemotherapy control rates.

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