Table 3. Objective Response Rate, According to Dosing Regimen and Status with Respect to Prior Therapy with Ipilimumab, as Assessed According to Two Criteria.

Table 3. Objective Response Rate, According to Dosing Regimen and Status with Respect to Prior Therapy with Ipilimumab, as Assessed According to Two Criteria.*

Regimen and Ipilimumab Status	RECIST				Immune-Related Response	
	No. of Patients	Confirmed and Unconfirmed Objective Response	Confirmed Objective Response	Duration of Response†	No. of Patients	Confirmed Objective Response
		no. (% [95% CI])		*mo*		*no. (% [95% CI])*
10 mg/kg every 2 wk						
No prior ipilimumab	39	21 (54 [37–70])	19 (49 [32–65])‡	1.9–10.8	41	23 (56 [40–72])
Prior ipilimumab	13	8 (62 [32–86])	8 (62 [32–86])§	2.8–8.3	16	9 (56 [30–80])
Total	52	29 (56 [41–69])	27 (52 [38–66])	1.9–10.8	57	32 (56 [42–69])
10 mg/kg every 3 wk						
No prior ipilimumab	19	7 (37 [16–62])	5 (26 [9–51])	2.6–5.6	24	8 (33 [16–55])
Prior ipilimumab	26	9 (35 [17–56])	7 (27 [12–48])	2.8–8.3	32	7 (22 [9–40])
Total	45	16 (36 [22–51])	12 (27 [15–42])	2.6–8.3	56	15 (27 [16–40])
2 mg/kg every 3 wk, no prior ipilimumab	20	7 (35 [15–59])	5 (25 [9–49])¶	2.1–5.5	22	3 (14 [3–35])
Total‖	117	52 (44 [35–54])**	44 (38 [25–44])	1.9–10.8	135	50 (37 [29–45])

* The efficacy population of patients with measurable disease was assessed by means of an independent, central, blinded radiologic review with the use of the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1, and by means of investigator assessment with the use of immune-related response criteria. The latter was the primary end point of the study. Responses based on immune-related response criteria included only those that were confirmed on two consecutive scans obtained at least 28 days apart.

† The duration of response was defined as the time from the first response to the time of documented progression or, in the case of censored data, the most recent tumor assessment. All the lower and upper ranges listed here are for censored data and refer to the time from the first response to the most recent tumor assessment, except for the lower range in the group with no prior ipilimumab, as well as the total cohort, receiving 10 mg per kilogram of body weight every 3 weeks; these two lower ranges refer to the time from first response to the time of documented progression. Only confirmed responses were included in the calculation of duration of response.

‡ Three of these patients had a complete response.

§ Two of these patients had a complete response.

¶ One of these patients had a complete response.

‖ The confirmed response rate, according to RECIST, version 1.1, was 38% (95% CI, 23 to 55) among patients who had received prior ipilimumab treatment and 37% (95% CI, 26 to 49) among patients who had not received prior ipilimumab treatment.

** Six patients with initial responses were awaiting confirmation of the response at the time of the data cutoff for this report. One response has since been confirmed, but since it was confirmed after the data cutoff for the current analysis, the data on overall response rate have not been modified.