confer clinical benefit. In 3-week cycles, patients received intratumoral MK-4621 0.4, 0.6, or 0.8 mg on days 1, 8, and 15 for 6 cycles (delivered via jetPEI®, Polyplus Transfection, Illkirch, France) plus intravenous pembrolizumab 200 mg on day 1 for 35 cycles. Treatment continued until disease progression or unacceptable toxicity. The primary objective was to establish a preliminary recommended phase 2 dose based on DLTs (cycle-1), AEs, and treatment discontinuations due to AEs; AEs were graded per NCI CTCAE v4.0. Tumor imaging was performed Q9W; response was assessed by the investigator.

Results As of May 14, 2020, 30 participants received therapy with MK-4621 0.4 (n=7), 0.6 (n=5), or 0.8 mg (n=18). Median time on therapy was 57 (range, 1-365) days. The most frequent tumor types were breast (20%) and melanoma (17%); 90% of patients received ≥2 prior lines of therapy. One patient in the 0.8-mg group experienced a DLT (grade 3 treatment-related pleural effusion), which resulted in treatment discontinuation; no other patient discontinued owing to AEs. Grade 3 treatment-related AEs occurred in 1 patient (14%) at the 0.4-mg dose (pyrexia), 1 patient (20%) at the 0.6-mg dose (hypertension), and 5 patients (28%) at the 0.8-mg dose (anemia [n=2], dyspnea/pleural effusion [n=1], lymphopenia [n=1], pyrexia [n=1]). No treatment-related grade 4/5 AEs occurred. Across dose levels, the most frequently occurring treatment-related AEs were pyrexia (63%), chills (37%), cough (25%), nausea (20%), immune-related AE (irAE), and 2 (12.5%) developed grade 3 or 4 irAEs. Grade 3-4 irAEs were ALT and AST increase and diarrhea. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an adverse event (AE), and 25% experienced a grade 3-4 AE. 68.8% experienced an 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