11516 **Poster Discussion Session**

A phase II basket trial of dual anti–CTLA-4 and anti–PD-1 blockade in rare tumors (DART) SWOG S1609: The desmoid tumors (cohort 27).

Young Kwang Chae, Megan Othus, Sandip Pravin Patel, Benjamin Powers, Chung-Tsen Hsueh, Rangaswamy Govindarajan, Silvana Z. Bucur, Liam Il-Young Chung, Christine McLeod, Helen X. Chen, Elad Sharon, Howard Streicher, Christopher W. Ryan, Charles David Blanke, Razelle Kurzrock; Northwestern University, Chicago, IL; Fred Hutchinson Cancer Center, Seattle, WA; UC San Diego Moores Cancer Center, La Jolla, CA; University of Kansas Medical Center, Kansas City, KS; Loma Linda University, Loma Linda, CA; University of Arkansas for Medical Sciences (UAMS), Little Rock, AR; St. Luke's Mountain States Tumor Institute, Meridian, ID; Northwestern University Feinberg School of Medicine, Chicago, IL; SWOG Data Operations Center, Seattle, WA; National Cancer Institute, Bethesda, MD; National Cancer Institute/National Institutes of Health, Bethesda, MD; OHSU Knight Cancer Institute, Portland, OR; Division of Hematology and Medical Oncology, Oregon Health and Science University, and SWOG Group Chair's Office, Portland, OR; Medical College of Wisconsin and WIN Consortium, Milwaukee, WI

Background: Dual inhibition with Anti-PD-1 and anti-CTLA4 checkpoint inhibitors is efficacious in many malignancies, but their potential role in numerous rare solid cancers is yet to be established. Desmoid tumors (DT; fibromatosis) are rare tumors of the soft tissue, and the mainstay of treatment is surgery (Richard Riedel, 2022). The utility of immunotherapy in this group of patients has not been explored. This study presents the first results of ipilimumab and nivolumab used in the DT cohort (#27) of the SWOG S1609 Dual Anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors (DART) trial. **Methods:** DART is a prospective, open-label, multicenter/multi-cohort phase 2 clinical trial of ipilimumab (1mg/kg intravenously every 6 weeks) plus nivolumab (240mg intravenously every 2 weeks). The primary endpoint includes objective response rate (ORR) (RECIST v1.1) (confirmed complete (CR) and partial responses (PR)). Secondary endpoints include progression-free survival (PFS), overall survival (OS), stable disease (SD) $>$ 6 months, and toxicity. **Results:** Sixteen evaluable patients (median age 37) with desmoid tumors were analyzed. Location of the tumors are: 8, abdomen; 3, lower limb: 2, upper limb; 2, pelvis; and 1, neck. ORR was 18.8% with 3 patients attaining PR: 40% regression with ongoing duration of response (DoR) at over 30+ months; 83% regression (PFS 16 months); and 71% regression (PFS of 8.4 months). Of note, 3 patients had SD (3/16, 18.8%) with some shrinkage of the tumors and a durable response; 23% regression with PFS of 1820+ days; 6% regression with PFS of 902 days; 1% regression with PFS of 1147+ days. Overall clinical benefit rate (CBR; no progression $>$ 6 months) was 62.5%. The median PFS was 17.9 months, 6-month PFS 69%, 1-year PFS 62%. All patients were alive at 1 years; median OS was not assessable as 14 patients are showing ongoing survival. The most common adverse events were fatigue (43.8%, n = 7), nausea (37.5%, n = 6), hypothyroidism (31.3%, n = 5), diarrhea, hyperthyroidism, headache, and adrenal insufficiency (25%, n = 4 each). There were 8 incidents (50%) of grade 3-4 adverse events. 7 adverse events led to discontinuation. There were no grade 5 adverse events. **Conclusions:** Ipilimumab plus nivolumab in treatment of desmoid tumors resulted in an ORR of 18.8% and CBR of 62.5% with durable responses seen. This is the first prospective study demonstrating efficacy of the combination in this rare disease. Correlative studies to determine response and resistance markers are ongoing. Expanded prospective studies in desmoid tumors are needed. Clinical trial information: NCT02834013. Research Sponsor: U.S. National Institutes of Health; Bristol-Myers Squibb.