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A Phase II single-arm study of PembrolizUmab plus Lenvatinib in previously treated classic Kaposi SARcoma(CKS): the PULSAR trial.

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Background

Classic Kaposi's sarcoma (CKS) is a cutaneous neoplasm of endothelial origin, caused by chronic human herpesvirus-8 (HHV-8) infection combined with an impaired immune function status. Systemic treatment of CKS is based on chemotherapy (CT), resulting in 30–50% of transient responses. There is a strong clinical need to assess the efficacy of new drugs for treatment of CKS. Pilot studies of anti-programmed cell death protein 1 (PD1) antibodies in CKS have shown promising results. Beside immunodeficiency status, HHV8 viral genes contribute to tumorigenesis through VEGF signaling pathways. Positive results of the combination of the anti-PD1 antibody, pembrolizumab, with the anti-angiogenic drug, lenvatinib, are supported by a strong biologic rationale and have been studied in several ongoing clinical trials in different types of solid tumors.

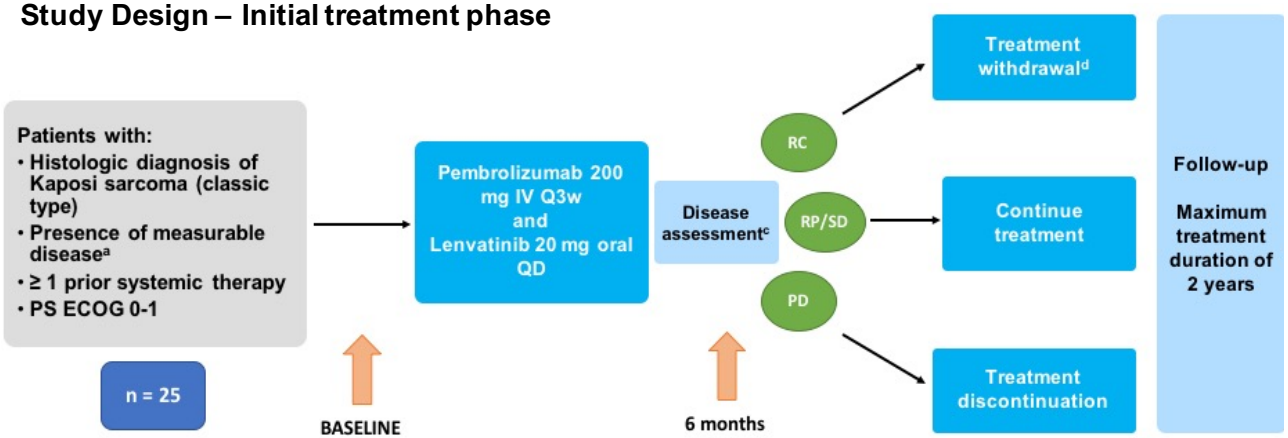
Main inclusion criteria include histologically confirmed diagnosis of CKS, and progression or inadequate response to ≥1 prior CT.
Exclusion criteria include known human immunodeficiency virus (HIV) infection.

Primary endpoint: overall response rate (ORR) [time frame: 6 months]

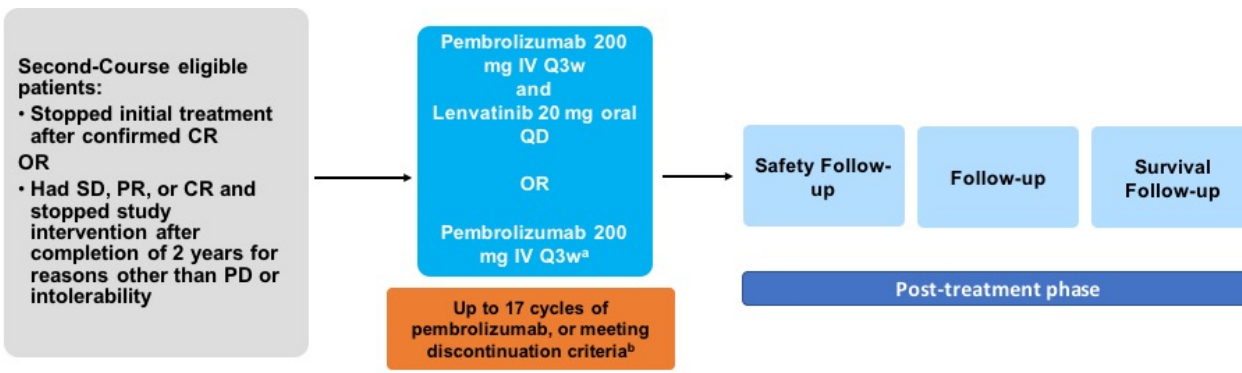
Secondary endpoints: Duration of response (DOR)
Progression-free survival (PFS)
Overall survival (OS)
Quality of life (QoL)
Safety and tolerability

Exploratory objectives: to evaluate changes in plasma levels of HHV8 DNA, PD-L1 and TILs in tumor specimens at baselina at the time of disease progression (optional)

Study Design – Initial treatment phase



Study Design – Second course treatment phase



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Clinical Trial Identification
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Protocol code: PULSAR
Protocol Number: MK 3475-B60