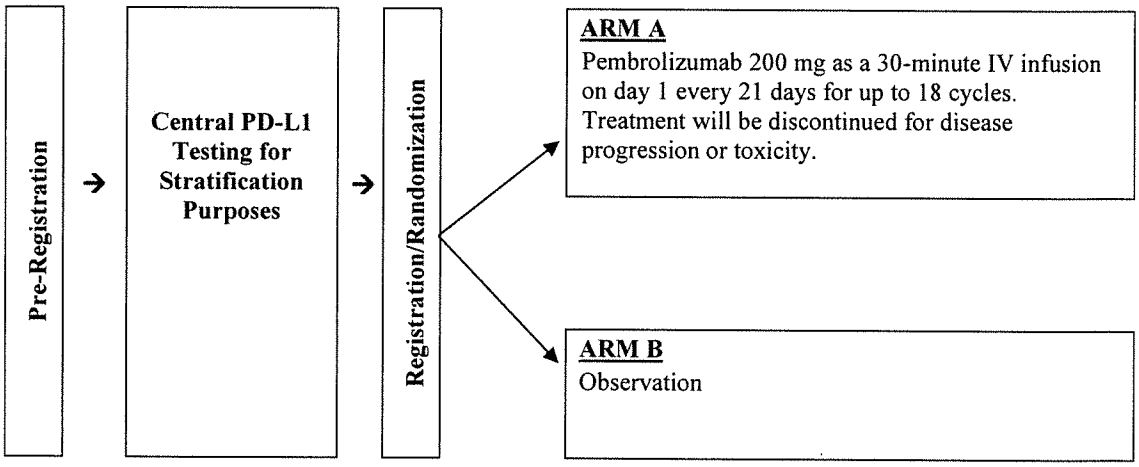
Phase III randomized "Adjuvant study of Pembrolizumab in muScle invaSive and locAlly aDvanced urOthelial caRcinoma" (AMBASSADOR) versus observation

Pre-registration Eligibility Criteria	Required Pre-registration Lab Values	
Histologically confirmed muscle-invasive urothelial carcinoma of the bladder or upper tract	Absolute Neutrophil Count (ANC)	$\geq$ 1,200/mm^3
Paraffin tissue available for PD-L1 analysis	Leukocytes	$\geq$ 3,000/ mm^3
Disease status per Section 3.2.3	Platelet Count	$\geq$ 75,000/mm^3
Radical resection of bladder cancer $\leq$16 weeks prior to pre-registration	Hemoglobin	$\geq$ 9 g/dL or $\geq$5.6 mmol/L
No evidence of residual cancer or mets after surgery	Calc. Creatinine Clearance	$\geq$ 30 ml/min
No measurable disease on cross-sectional imaging		
No active autoimmune disease or history of autoimmune disease that may recur	Total Bilirubin Bilirubin for pts w/ Gilbert's	$\leq$ 1.5 x ULN $\leq$ 3.0 x ULN
No current or history of pneumonitis	AST/ALT	$\leq$ 3.0 x ULN
No known active Hepatitis B or C	Serum Albumin	$\geq$ 2.8 g/dL
No postoperative/adjuvant systemic therapy		
No prior treatment with any therapy on the PD-1 Or PD-L1 axis		
No, treatment with an investigational agent, major surgery, radiation therapy or neoadjuvant chemotherapy $\leq$4 weeks prior to pre-registration		
Age $\geq$18 years; Non-pregnant and non-nursing; ECOG PS 0-2		
Registration Eligibility Criteria		
Central PD-L1 results available		

Schema
1 Cycle = 21 Days



Treatment is to continue until metastatic recurrence or unacceptable toxicity for up to 18 cycles. Metastatic recurrence is defined by a new lesion on CT scan. Patients will be followed for a total of 5 years from the date of registration or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.