[Date], 2021

Dear Research Participant (or Name):

You are receiving this letter because you are currently participating in a research study called Alliance A031501, “Phase III Randomized Adjuvant Study of Pembrolizumab in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) versus Observation.”

Recently, the U.S. FDA approved a drug called nivolumab for adjuvant therapy to help delay or prevent recurrent cancer in patients who have had surgery to remove urothelial cancer in the bladder, renal pelvis or ureter.

**How does this impact A031501?**

Nivolumab is an anti-PD1 checkpoint inhibitor, similar to pembrolizumab, which is the drug being used in the research study you are enrolled in. As a result of the FDA approval of nivolumab, registration of new patients to A031501 was stopped on August 24th, 2021. However, the trial will continue to collect data and gather information from patients who are already enrolled.

**What are your options?**

Possible future options for you would be to continue with the group you were registered to (treatment with pembrolizumab or continue without treatment). You may also have the option to start treatment with the newly approved FDA drug nivolumab if you are within 120 days of your surgery.

As with any research study, you always have the right to stop participating at any time by informing your study doctor of your choice.

**Ask your doctor:**

Any further treatment will be a decision made between you and your doctor.

Regardless of the treatment option that you choose, remaining enrolled in the study will allow us to continue to collect as much information as possible about your progress. This information will continue to help us understand and treat this disease.

You are a very important part of this study, and we thank you for participating.