

Merck, Pfizer publish results from Ph III JAVELIN bladder 100 study

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The results were published simultaneously with additional analyses being presented at the ESMO Virtual Congress 2020



Merck and Pfizer Inc. have recently announced the publication of detailed results from the Phase III JAVELIN Bladder 100 study online ahead of print in *The New England Journal of Medicine*.

These results were published simultaneously with additional analyses being presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 and describe the efficacy of BAVENCIO® (avelumab) as a first-line maintenance treatment across various subgroups of patients with locally advanced or metastatic urothelial carcinoma (UC) and highlight exploratory biomarkers as well as patient-reported outcomes.

In June, the US Food and Drug Administration (FDA) approved BAVENCIO for the maintenance treatment of patients with locally advanced or metastatic UC that has not progressed with first-line platinum-containing chemotherapy based on the JAVELIN Bladder 100 results.

In the JAVELIN Bladder 100 study, BAVENCIO plus best supportive care (BSC) significantly extended overall survival (OS) compared with BSC alone in the two primary populations of all randomized patients and patients whose tumors were PD-L1+, and significantly more patients who received BAVENCIO as first-line maintenance were alive at one year. The clinical benefits of BAVENCIO were seen across a range of patient populations.

In the JAVELIN Bladder 100 study, OS was significantly longer with BAVENCIO plus BSC compared to BSC alone in the primary population of all randomized patients (n=700) whose disease had not progressed on first-line platinum-containing chemotherapy.

Results of an exploratory subgroup analysis show that consistent results were observed with the JAVELIN Bladder regimen of BAVENCIO first-line maintenance across pre-specified subgroups, including best response to first-line chemotherapy, type of chemotherapy regimen, site of baseline metastasis, and other baseline factors.