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EU approves BAVENCIO® (avelumab) Plus Axitinib to treat RCC

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EU approval based on JAVELIN Renal 101 trial results demonstrates significant improvement in patients with advanced Renal Cell Carcinoma for a progression-free survival

Merck and Pfizer Inc. on 29 Oct 2019, announced that the European Commission (EC) has approved BAVENCIO® (avelumab) in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC). The approval was based on positive interim results from the Phase III JAVELIN Renal 101 study, which demonstrated that BAVENCIO in combination with axitinib significantly lowered risk of disease progression or death by 31% (HR: 0.69 [95% CI: 0.574-0.825; p<0.0001]) and nearly doubled objective response rate (ORR; 52.5% [95% CI: 47.7-57.2] vs. 27.3% [95% CI: 23.2-31.6]) compared with sunitinib in patients with advanced RCC regardless of PD-L1 status. The study included patients across International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), prognostic risk groups. Improvement in progression-free survival (PFS) was observed across prespecified subgroups in patients receiving the treatment combination. Merck and Pfizer have a global strategic alliance to jointly develop and commercialize BAVENCIO.

"There is a high incidence of kidney cancer in Europe, and for the most common type, renal cell carcinoma, we continue to need additional treatment options, particularly for patients with advanced disease, where outcomes are poorest," said Professor James Larkin, Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust and Professor at the Institute of Cancer Research (ICR). "We've seen a demonstrated efficacy benefit and safety and tolerability profile for avelumab in combination with axitinib across all prognostic risk groups in patients with advanced renal cell carcinoma, so today's approval in Europe brings an important option that can help healthcare professionals optimize treatment strategies across risk stratification."

In 2018, an estimated 136,500 new cases of kidney cancer were diagnosed in Europe, and approximately 54,700 people died from the disease. Many patients living with advanced RCC do not go on to receive additional treatment after first-line therapy, for reasons that may include poor performance status or adverse events from their initial treatment. The five-year survival rate for patients with advanced RCC is approximately 12%.

"This first European approval of an anti-PD-L1 as part of a combination treatment for advanced renal cell carcinoma builds on our commitment to bringing innovative treatment options to patients with hard-to-treat cancers through our extensive

JAVELIN clinical trial program," said Rehan Verjee, Global Head of Innovative Medicine Franchises for the Biopharma business of Merck. "RCC is the most common form of kidney cancer, accounting for 90% of diagnoses. We are now working to make BAVENCIO in combination with axitinib available for patients with advanced renal cell carcinoma as quickly as possible."

"The European Commission approval of BAVENCIO in combination with axitinib has the potential to bring even more patients with advanced renal cell carcinoma a new first-line treatment, and it allows us to continue to deliver on our more than decade-long passion to do more for patients with kidney cancer," said Andy Schmeltz, Global President, Pfizer Oncology. "We thank all of the researchers, doctors, advocates, patients and their families who helped get us here today, and we will continue in our fight against this advanced cancer."

The EC's decision follows the U.S. Food and Drug Administration (FDA) approval of BAVENCIO in combination with axitinib for the first-line treatment of patients with advanced RCC in May 2019. A supplemental application for BAVENCIO in combination with axitinib in unresectable or metastatic RCC was submitted in Japan in January 2019.

Additionally, with this approval, the posology section of the Summary of Product Characteristics for BAVENCIO has been updated. The recommended dose of BAVENCIO as monotherapy is 800 mg administered intravenously over 60 minutes every 2 weeks. Administration of BAVENCIO should continue according to the recommended schedule until disease progression or unacceptable toxicity. The recommended dose of BAVENCIO in combination with axitinib is 800 mg administered intravenously over 60 minutes every 2 weeks and axitinib 5 mg orally taken twice daily (12 hours apart) with or without food until disease progression or unacceptable toxicity.