Bavencio® (avelumab) – New indication

- On May 14, 2019, EMD Serono and Pfizer announced the FDA approval of Bavencio (avelumab), in combination with Inlyta® (axitinib) for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

- Bavencio is also approved for the treatment of metastatic Merkel cell carcinoma and locally advanced or metastatic urothelial carcinoma.

- In 2019, an estimated 73,820 new cases of kidney cancer will be diagnosed in the U.S., and approximately 14,770 people will die from the disease. RCC is the most common form of kidney cancer, accounting for about 2% to 3% of all cancers in adults. The five-year survival rate for patients with metastatic RCC is approximately 12%.

- The efficacy of Bavencio in combination with Inlyta was demonstrated in the JAVELIN Renal 101 study, an open-label study in 886 patients with untreated advanced RCC. Patients were randomized to receive Bavencio plus Inlyta or Sutent® (sunitinib). The major efficacy outcome measures were progression-free survival (PFS) and overall survival (OS).

    — Median PFS was 13.8 months and 8.4 months for Bavencio plus Inlyta and Sutent, respectively (Hazard Ratio 0.69; 95% CI: 0.56, 0.84; p = 0.0002).
    — With a median OS follow-up of 19 months, OS data were immature with 27% deaths in the intent-to-treat population.
    — In addition, the confirmed objective response rate was 51.4% (95% CI: 46.6, 56.1) and 25.7% (95% CI: 21.7, 30.0) for Bavencio plus Inlyta and Sutent, respectively.

- The most common adverse reactions (> 20%) for Bavencio plus Inlyta use in patients with RCC were diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain, and headache.

- The recommended dose of Bavencio for the treatment of RCC is 800 mg administered as an intravenous infusion over 60 minutes every 2 weeks in combination with Inlyta 5 mg orally taken twice daily with or without food until disease progression or unacceptable toxicity.

    — When Inlyta is used in combination with Bavencio, dose escalation of Inlyta above the initial 5 mg dose may be considered at intervals of two weeks or longer. Refer to Inlyta's drug label for additional dosing recommendations.
    — Refer to the Bavencio drug label for dosing for all its other indications.