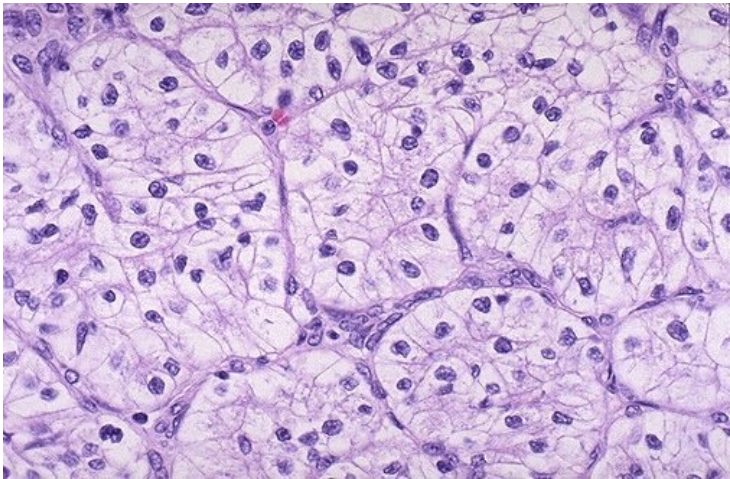


USFDA accepts Merck and Pfizer's sBLA for Renal Cancer drug

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Merck and Pfizer Inc. has announced that the US Food and Drug Administration (FDA) has accepted for Priority Review the supplemental Biologics License Application (sBLA) for BAVENCIO[®] (avelumab) in combination with INLYTA[®] (axitinib) for patients with advanced renal cell carcinoma (RCC). The application has been given a target action date in June 2019.

"The combination of BAVENCIO with INLYTA builds on Pfizer's significant heritage in advancing standards of care for patients with advanced RCC and has the potential to make a meaningful impact for the lives of patients," said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. "We look forward to working with the FDA to bring this potential new treatment option to patients as quickly as possible."

"Our alliance is focused on the development of potential new treatment options for patients with cancers that have high unmet medical needs, including the broad spectrum of people living with advanced RCC," said Luciano Rossetti, M.D., Executive Vice President, Head of Global Research & Development at the Biopharma business of Merck. "This regulatory milestone, which closely follows the acceptance of our application in Japan, represents an important step forward for science and for patients."

The submission is based on data from the pivotal Phase III JAVELIN Renal 101 trial, which were presented in a Presidential Symposium at the European Society of Medical Oncology (ESMO) 2018 Congress in Munich. In December 2017, the FDA granted Breakthrough Therapy Designation for BAVENCIO in combination with INLYTA for treatment-naïve patients with advanced RCC.

The clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs and more than 9,000 patients evaluated across more than 15 different tumor types. In addition to RCC, these tumor types include breast, gastric/gastro-esophageal junction, and head and neck cancers, Merkel cell carcinoma, non-small cell lung cancer, and urothelial carcinoma.

The combination of BAVENCIO and INLYTA is under clinical investigation for advanced RCC.