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Merck and Pfizer has announced that the US Food and Drug Administration (US FDA) has granted avelumab, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, Breakthrough Therapy designation for the treatment of patients with metastatic Merkel cell carcinoma (MCC) who have progressed after at least one previous chemotherapy regimen.

Breakthrough Therapy designation is designed to accelerate the development and review of medicines that are intended to treat a serious condition, and preliminary clinical evidence indicates that the therapy may demonstrate a substantial improvement over current available therapies. MCC is a rare and aggressive type of skin cancer. Each year, there are approximately 1,500 new cases of MCC diagnosed in the US. There is currently no therapy approved specifically for the treatment of metastatic MCC.

The Breakthrough Therapy designation is based on the preliminary evaluation of clinical data from the global Phase II study, JAVELIN Merkel 200, which is assessing the safety and efficacy of avelumab in patients with metastatic MCC whose disease has progressed after at least one prior chemotherapy regimen. Results from this Phase II study are planned for presentation at upcoming scientific congresses in 2016. The designation represents a significant milestone and has the potential to speed the development of avelumab for metastatic MCC patients.

JAVELIN Merkel 200 is a multicenter, single-arm, open-label Phase II study with a primary objective of overall response rate. Secondary endpoints include duration of response, progression-free survival, overall survival and safety. The study, which enrolled 88 patients, is being conducted in sites across Asia Pacific, Australia, Europe and North America.

"Metastatic Merkel cell carcinoma is a devastating disease with limited treatment options currently available for patients," said Dr Luciano Rossetti, global head of R&D of the biopharma business of Merck. "With this Breakthrough Therapy designation, we are one step closer to our goal of making a significant difference to patients living with difficult-to-treat cancers, such as

metastatic Merkel cell carcinoma, by researching and developing potential new treatment options."

"In less than two months, the alliance between Merck and Pfizer has achieved its third regulatory milestone for avelumab, including Orphan Drug designation and Fast Track designation granted in September and October," said Dr Mace Rothenberg, senior vice president of clinical development and medical affairs and chief medical officer for Pfizer Oncology. "We are very pleased with the progress of the JAVELIN clinical development program and we are looking forward to presenting additional data on the potential of this investigational compound in Merkel cell carcinoma and other tumor types in 2016."

The clinical development program for avelumab now includes more than 1,400 patients who have been treated across more than 15 tumor types, including breast cancer, gastric/gastro-esophageal junction cancers, head and neck cancer, MCC, mesothelioma, melanoma, non-small cell lung cancer, ovarian cancer, renal cell carcinoma and urothelial (e.g., bladder) cancer.