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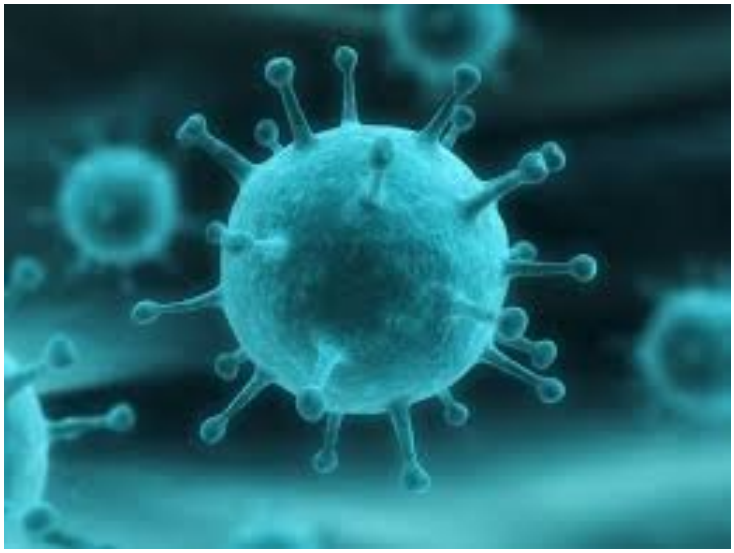

Merck KGaA and Pfizer's Phase III JAVELIN Renal 101 trial, which will assess the combination of the checkpoint inhibitor avelumab and Pfizer's anti-angiogenesis tyrosine kinase inhibitor (TKI) Inlyta (axitinib) in the first-line renal cell carcinoma (RCC) setting, is the most likely immunotherapy combination to be first to market in the treatment space, according to an analyst with research and consulting firm GlobalData.

As explored in the company's latest RCC report, Bristol Myers Squibb's (BMS) checkpoint inhibitor Opdivo (nivolumab) will be an important driver of growth over the next few years.

After the drug's approval in November 2015 in the US and February 2016 in Europe, it established immunotherapy as the new standard of care in recurrent RCC.

Dr Maxime Bourgognon, GlobalData's Analyst covering Oncology and Hematology explains: "BMS is trialing Opdivo in combination with another checkpoint inhibitor, Yervoy (ipilimumab), an approach that results in a synergistic mechanism of action. This is different to Merck KGaA and Pfizer's use of TKIs, which has shown the ability to reduce myeloid-derived suppressor cells, alleviating the immunosuppression by the tumor and enhancing the efficacy of immunotherapies.

"It is difficult to accurately predict which approach is clinically more promising; however, GlobalData believes that the safety profiles of the combination agents will play a key role in their establishment as standard of care in first-line RCC. Indeed, Inlyta is one of the safest TKIs currently approved for RCC, making its combination with avelumab promising.

"In comparison, combining the checkpoint inhibitors Opdivo and Yervoy could alter their safety profiles, as has been seen in melanoma, where the combination is approved with a boxed warning for severe and fatal immune-mediated adverse reactions. The Inlyta and avelumab combination also holds a distinct advantage in that it is likely to hit the market before BMS's combination."

Combination approaches have the potential to generate twice as many sales in the recurrent RCC market as Opdivo, by increasing the number of patients able to benefit from immunotherapies and extending the length of time during which patients receive immunotherapy treatment.

Dr Bourgognon concludes: "GlobalData anticipates that the launch of combinations with checkpoint inhibitors will have a major impact to the RCC treatment paradigm, with the avelumab and Inlyta combination becoming the standard of care due to its first-to-market position and its synergistic efficacy and safety attributes."