

## Bayer, Bristol-Myers Squibb and Ono Pharma enter into clinical collaboration

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**Under clinical collaboration agreement companies to investigate Stivarga® (regorafenib) and Opdivo® (nivolumab) as combination therapy in patients with metastatic colorectal cancer**



Bayer, Bristol-Myers Squibb Company and Ono Pharmaceutical Co., Ltd. have entered into a clinical collaboration agreement to evaluate the combination of Bayer's kinase inhibitor Stivarga® (regorafenib) and Bristol-Myers Squibb's / Ono's anti-PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab) in patients with micro-satellite stable metastatic colorectal cancer (MSS mCRC), the most common form of mCRC.

Regorafenib as monotherapy has demonstrated an overall survival benefit versus placebo in the pivotal Phase III CORRECT study and has shown activity irrespective of micro-satellite status in a retrospective analysis from this study, though with limited responses observed. Despite progress in the treatment of CRC, including the advance of effective immuno-oncology (I-O) treatments for certain subsets of CRC, around 95% of mCRC patients have MSS tumors, for which I-O monotherapy treatment approaches have shown limited activity.

Thus, the need for additional treatment options including combination approaches remains high. Encouraging early data have been seen with the combination of regorafenib and nivolumab. In a Phase 1b investigator sponsored trial from Japan called REGONIVO (NCT03406871, EPOC1603), the combination of regorafenib and nivolumab has shown promising preliminary efficacy results. The detailed data of the study were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

Further terms of the clinical collaboration were not disclosed.