

3 The current status of immune checkpoint blockade therapy

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Increased understanding of tumor immunology over the past two decades has enabled the identification of innovative ways to improve the immune response to cancer, providing immunotherapies that can improve survival. This talk will focus on the clinical development of nivolumab, Opdivo, as monotherapy and in combination with other immuno-oncology agents. In 2011, Bristol-Myers Squibb introduced Yervoy™, a CTLA-4 inhibitor, the first immuno-oncology medicine brought to market for metastatic melanoma. In 2014, the ONO-BMS collaboration introduced to the market a new immuno-therapy, Opdivo™, an anti-PD1 immune checkpoint inhibitor. In clinical studies, Opdivo is the first anti-PD1 to demonstrate meaningful overall survival in malignant melanoma, non-small cell lung cancer (NSCLC), and renal cell cancer in different lines of therapy and histologies. Global studies have proven clinical benefit compared to conventional chemotherapy for the two monotherapies and for the combination of Opdivo + Yervoy. The clinical results establish the role of PD-L1 expression. In non-squamous NSCLC, survival of patients doubled compared to chemotherapy among PD-L1 expressors. In squamous NSCLC, clinical benefit was shown regardless of PD-L1 expression. The combination of Opdivo + Yervoy in malignant melanoma further enhances efficacy, in particular for PD-L1 low and non-expressors. The safety characteristics of immunotherapy that was learned from these clinical trials will also be described. Currently there are three new Immuno-Oncology agents in the clinic (Lirilumab, Urelumab, Anti-LAG3) and four additional agents expected in the next six to twelve months. Anti-PD-1 therapy will be a foundation of future combination regimens that have the potential to set a new standard in cancer care.