Kantonsspital St.Gallen

A Phase 1/2a Dose Escalation and Cohort Expansion Study for Safety, Tolerability, and Efficacy of BMS-986156 Administered Alone and in Combination with Nivolumab (BMS-936558, anti PD-1 Monoclonal Anti-body) in Advanced Solid Tumors

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This is a Phase 1/2a, open-label study of BMS-986156 administered as a single agent and in combination with nivolumab in subjects with advanced solid tumors. The study will be conducted in 4 parts. Parts A and B will consist of dose escalation with BMS-986156 administered as a single agent (Part A) or in combination with nivolumab (Part B) in subjects with advanced solid tumors. Starting dose selection of BMS-986156 for Part B will be determined using all available safety (clinical and laboratory), PK, and PD data and will be one dose level lower than a dose already tested and shown to be tolerated in ongoing monotherapy dose escalation in Part A (See Section 1.1.4, Appendix 1 for details); subsequently, escalation in the 2 parts will proceed in parallel. Nivolumab will be adminis-tered as a dose of 240 mg administered every 2 weeks for all combination dose cohorts (Parts B and D).
Cohort expansions will be evaluated with BMS-986156 monotherapy (Part C) and combination therapy (Part D). Each cohort expansion arm will consist of approximately 25 subjects. Part C consists of cohort expansions with BMS-986156 monotherapy in 2 disease-restricted populations: (i) NSCLC subjects with progressive or recurrent disease during or after prior platinum doublet-based chemotherapy, followed by recurrent or progressive disease (per RECIST v1.1) during or after subsequent anti-PD-1 or anti-PD-L1 therapy, and (ii) persistent, recurrent or metastatic cervical cancer. Part D consists of cohort expansion with BMS-986156 administered in combination with nivolumab in 3 diseaserestricted populations as follows: (i) NSCLC subjects with progressive or recurrent disease during or after prior platinum doublet-based chemotherapy followed by progressive or recurrent disease (per RECIST v1.1) during or after subsequent anti-PD-1 or anti-PD-L1 therapy (ii) NSCLC subjects with progressive or recurrent disease during or after platinum doublet-based chemotherapy with no prior anti-PD-1 or anti-PD-L1 therapy, and (iii) persistent, recurrent or metastatic cervical cancer. Additional tumor types such as bladder cancer, head and neck squamous cell cancer, ovarian cancer, hepatocellular carcinoma and others may be explored in Part D. Treatment in

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Parts C and D will be initiated when the MTD/MAD/alternate dose has been determined.

type of project	clinical studies
status	ongoing - follow up
start of project	2016
end of project	2017
study design	Phase I
responsible person	PD Dr. med. Markus Jörger