



Investigator-Sponsored Studies in the area of immuno-oncology are supported by Merck and Pfizer Inc. in connection with their strategic alliance (“Alliance”) to co-develop and co-commercialize avelumab, a human anti-PD-L1 IgG1 monoclonal antibody.

In general, the Alliance will give priority to investigator-sponsored study proposals that aim to explore the following:

- Safety and efficacy of novel combinations with avelumab and/or sequencing based on strong scientific rationale and developing trends in the field (monotherapy trials will be de-prioritized)
- Use of avelumab in early stage disease
- Further understanding of the clinical usefulness of engaging the innate immune system with avelumab
- Adequate management of immune-mediated AEs and infusion-related reactions
- Combinatorial synergy with avelumab and other checkpoint inhibitors
- Duration of therapy evaluations
- Definition/identification of responders in the ‘tail of the curve’
- Understanding of primary, adaptive, and/or acquired resistance to IO therapy
- Identification of other biomarkers

Preference will also be given to the following tumor types based on the timeline below:

- Merkel Cell Carcinoma (MCC)
- Non-Small Cell Lung Cancer (NSCLC)
- Squamous Cell Carcinoma of the Head & Neck (SCCHN)
- Ovarian Cancer
- Gastric Cancer
- Renal Cell Carcinoma (RCC)
- Urothelial Carcinoma (UC)
- Hodgkin and Non-Hodgkin Lymphoma

Special Submission and Review Schedule*

The Global Review Committee for the Alliance reviews study proposals at quarterly meetings, with particular tumor types assigned to each quarterly meeting (see assignments below). Study proposals for each tumor type will generally be reviewed once a year, and not until the assigned quarterly meeting.

Carefully review the submission deadline for the particular tumor type you propose to study with avelumab. If a submission deadline is missed, your study proposal may not be considered until the next calendar year.

Focused Area of Interest*	Submission Deadlines*	Quarterly Review
NSCLC, Ovarian/Gynecological, UC, and RCC	30 July 2018 Pfizer 02 August 2018 Merck	September 2018
Hodgkin and Non-Hodgkin Lymphoma, MCC, and Other tumor types not covered at other quarterly meetings	30 September 2018 Pfizer 23 October 2018 Merck	December 2018
Gastric and SCCHN	28 January 2019 Pfizer 05 February 2019 Merck	March 2019

****Check back frequently to the web-based submission portal as these areas of interest and/or the submission and review schedule are subject to change.***

For more information and for proposal submission, navigate to either:

www.iss.merckbiopharma.com or www.pfizer.com/iir

Please contact your Merck or Pfizer Field Medical Representative for additional information.