# Question 13 – Detail of clinical studies

**(For industry/clinical groups)** Clinical study information:

| Question 13 a - Submission to August 2018 PBAC meeting – Detail of PD-1 and PD-L1 inhibitor clinical studies | | | | | | | | |
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| Study name | ClinicalTrials.gov or other identifier – please indicate the organisation | Company trial identifier | Indication/s | Intervention/s (please include all trial arms) | Trial start date (or anticipated start date) | Expected trial end date | Link to latest published results (if available?) | Intent to seek PBS subsidy? (Yes/No/ Unsure) If yes, anticipated date? |
| Randomized, Open-label, Phase 3 Trial of Nivolumab plus Brentuximab vedotin versus Brentuximab vedotin alone in Participants with Relapsed Refractory or Ineligible for Autologous Stem Cell Transplant (ASCT) Advanced Stage Classical Hodgkin Lymphoma (CheckMate 812: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 812) | NCT03138499 | Study #2017-0974 | relapsed or refractory advanced stage classical Hogdkin lymphoma (cHL) who are not eligible for a stem cell transplant | * brentuximab vedotin alone * brentuximab vedotin in combination with nivolumab | IRB approval 5/11/2017, currently recruiting |  |  |  |
| A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with >/= 1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy | NCT02954874 | Study #SWOGS1418 | Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with >/= 1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy | * no treatment for 12 months beyond monitoring. May undergo radiation therapy within 12 weeks of last breast cancer operation or after treatment * pembrolizumab specified dose and days. May undergo radiation therapy within 12 weeks of last breast cancer operation or after treatment | IRB approval 5/31/2017, currently recruiting |  |  |  |
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* Please complete the tables below to inform your response to question 13 of your submission.
* Please complete the table below to include all studies which your organisation has completed, is currently conducting, or planning to conduct, with a PD-1 and/or PD-L1 inhibitor irrespective of whether a positive outcome was observed, including the indication/s and intention to seek PBS subsidy.
* Please note the two example studies included in the table below.

| Question 13 b - Submission to August 2018 PBAC meeting |
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| * How does your organisation decide which indications to study and which to prioritise for registration or subsidy? |
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