# Attachment A

## Summary of PD-1 and PD-L1 registration and reimbursement dates

### Drug: nivolumab [Opdivo, BMSA]

Bolded PBAC consideration dates = positive recommendation

| **Indication** | **FDA Approval** | **EMA approval (CHMP positive opinion)** | **TGA evaluation commenced** | **TGA approval** | **PBAC consideration** | | | **PBS listing** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First** | **Second** | **Third and subsequent** |
| Treatment of patients with unresectable or metastatic melanoma | 22 December 2014 | 24 September 2015 | '''' ''''''''''''''''''''' ''''''''''' | 11 January 2016 | July 2015 | **November 2015** | - | 1 May 2016 |
| Adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection | 20 December 2017 | 28 June 2018 | 23 October 2017 | 23 April 2018 | July 2018 | March 2019 |  |  |
| Treatment of locally advanced or metastatic squamous NSCLC with progression on or after prior chemotherapy | 4 March 2015 | 24 September 2015 | ''' '''''''''''''''''''' '''''''''''' | 11 January 2016 | March 2016 | November 2016 | **March 20171** | 1 August 2017 |
| Treatment of locally advanced or metastatic non-squamous NSCLC with progression on or after prior chemotherapy. | 9 October 2015 | 25 February 2016 | ''''' '''''''''''''''''''''''' ''''''''''' | 17 February 2016 | March 2016 | November 2016 | **March 20171** | 1 August 2017 |
| Treatment of patients with advanced clear RCC after prior anti-angiogenic therapy | 23 November 2015 | 25 February 2016 | '''' ''''''''''''''''''''' ''''''''''' | 18 November 2016 | July 2016 | November 2016 | **March 20172** | 1 August 2017 |
| Treatment of patients with relapsed or refractory cHL after autologous stem cell transplant and treatment with brentuximab vedotin | 17 May 2016 | 13 October 2016 | 31 May 2016 | 25 May 2017 | November 2017 (withdrawn prior to consideration) |  |  |  |
| Treatment of recurrent or metastatic squamous cell cancer of the head and neck in patients progressing on or after platinum-based therapy | 10 November 2016 | 23 March 2017 | 2 September 2016 | 7 July 2017 | November 2017 | **March 2018** |  | 1 August 2018 |
| Treatment of patients with locally advanced unresectable or metastatic urothelial carcinoma after prior platinum-containing therapy | 2 February 2017 | 21 April 2017 | 31 January 2017 | 6 February 2018 |  |  |  |  |
| In combination with ipilimumab for the treatment of patients with unresectable or metastatic melanoma3 | 30 September 2015 | 1 April 2016 | ''' ''''''''''''''''''' ''''''''''''/  1 August 2017 | 7 January 2016/  4 July 2018 | November 20153 | March 20173 | **July 2018** | 1 December 2018 |
| In combination with ipilimumab, for the treatment of patients with intermediate/poor-risk, previously untreated advanced RCC | 16 April 2018 | 15 November 2018 | 28 February 2018 | 31 October 2018 | July 2018 | **November 2018** |  |  |
| Treatment of patients with hepatocellular carcinoma after prior sorafenib therapy | 22 September 2017 | withdrawn | 1 August 2017 | 17 September 2018 |  |  |  |  |
| '''''''''''''''''''''''''' ''''' ''''''''''''' ''''''''''''''''''' '''''''''' ''''''''''''''''''''''' ''''' '''''''''''''''''''' ''''''''''''''''' '''' ''''''''''''''''''''''''''''''''''''''''''''' ''''''''''''''''' ''''''''''''''''' ''''''''''' '''''''' '''' '''''''''''''' ''''''''''' '''''''''''''''''''''' '''''''''''''''''''''' |  |  | '''''' '''''''''''''''''''''''''' ''''''''''' |  |  |  |  |  |
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1. Combined non-squamous and squamous consideration

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1. Initial indication approved in January 2016 included requirement for M1c disease or elevated lactic dehydrogenase

### Drug: pembrolizumab [Keytruda, MSD]

Bolded PBAC consideration dates = positive recommendation

| **Indication** | **FDA Approval** | **EMA approval (CHMP positive opinion)** | **TGA evaluation commenced** | **TGA approval** | **PBAC consideration** | | | **PBS listing** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First** | **Second** | **Third and subsequent** |
| Unresectable or metastatic melanoma in adults | 18 December 2015 | 21 May 2015 | ''''' '''''''''''''''' '''''''''''' | 16 April 2015 | **March 2015** |  |  | 1 September 2015 |
| First-line treatment of patients with metastatic NSCLC whose tumours express PD-L1 with a greater than or equal to 50% tumour proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumour aberrations | 24 October 2016 | 15 December 2016 | 30 September 2016 | 3 March 2017 | March 2017 | November 2017 | March 2018  **July 2018** | 1 November 2018 |
| In combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC | 10 May\* 2017 | 26 July 2018 | 2 May 2017 | 8 June 2018 | November 2018 |  |  |  |
| Treatment of patients with advanced NSCLC whose tumours express PD-L1 with a greater than or equal to 1% TPS as determined by a validated test and who have received platinum-containing chemotherapy. | 24 October 2016 | 23 June 2016 | 30 September 2016 | 3 March 2017 | November 2016 |  |  |  |
| Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy | 5 August 2016 | 26 July 2018 | 30 June 2016 | 20 March 2017 | July 2018 |  |  |  |
| Relapsed or refractory classical Hodgkin’s Lymphoma: 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option. | 15 March 2017 | 23 March 2017 | 31 October 2016 | 1 September 2017 | July 2017 | **August 2017** |  | 1 May 2018 |
| Locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy | 18 May 2017 | 20 July 2017 | 28 February 2017 | 9 January 2018 |  |  |  |  |
| Locally advanced or metastatic urothelial carcinoma who have received platinum-containing chemotherapy | 18 May 2017 | 20 July 2017 | 28 February 2017 | 9 January 2018 | November 2017 | **July 2018** |  |  |
| Treatment of adult and paediatric patients with refractory primary mediastinal B-cell lymphoma, or who have relapsed after 2 or more prior lines of therapy | 13 June 2018 |  | 31 January 2018 | 19 October 2018 | November 2018 |  |  |  |
| Adjuvant treatment of patients with melanoma with lymph node involvement who have undergone complete resection |  |  | '''' ''''''''''''' ''''''''''''' | Pending (as at November 2018) | November 2018 |  |  |  |
| Treatment of patients with advanced microsatellite instability-high (MSI-H), including mismatch repair deficient (dMMR) cancer who have received prior therapy | 23 May 2017 |  | '''''' ''''''''' '''''''''''' |  | March 2019 (Colorectal cancer only) |  |  |  |
| ''''' ''''''''''''''''''''''''''''' ''''''''' '''''''''''''''''''''''' ''''''''' ''''''''''''' '''''''''''''''''''''''' ''''' ''''''''''''''''''''''''''''' '''''''''''''''''''''''''''''''' '''''''''''''''''''''''' ''''''' ''''''''' ''''''''''''''''' '''''''''''''''''''' '''' '''''''''''''''''' ''''''''' ''''''''''''''''''''''' ''''''''''''''''''''''''' '''''''''''''''''''' | ''''''' ''''''''''''''''' ''''''''''''' |  | ''' '''''''''''''''''''''''' ''''''''''''' |  |  |  |  |  |

An additional 2 PBAC submissions were related to the Deed of Agreement and 2 were related to changes to the listing

\*date accelerated FDA approval granted

### Drug: atezolizumab [Tecentriq, Roche]

Bolded PBAC consideration dates = positive recommendation

| **Indication** | **FDA Approval** | **EMA approval (CHMP positive opinion)** | **TGA evaluation commenced** | **TGA approval** | **PBAC consideration** | | | **PBS listing** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First** | **Second** | **Third and subsequent** |
| Locally advanced or metastatic NSCLC with progression on or after prior chemotherapy. | 18 October 2016 | 20 July 2017 | 31 July 2016 | 26 July 2017 | **November 2017** |  |  | 1 April 2018 |
| ''''''''''''''''''''''' ''''' '''''''''''''''''''' '''''''''' ''''''''''''''' ''''''''''''''''''''''' '''''' '''''''''''''''''''''' '''''''''''''''''''''''' ''''''''''''''''''''''' '''''''''' '''''''''' '''''''''''''''''''''''''''''''''''' '''''' '''''''''' ''''''''' '''''''''''''''''''''''' '''''''''''''''''''''' '''''''''''''''''''' | '''''' '''''''''' '''''''''''' | ''''' '''''''''' '''''''''''' | '''' '''''''''''' '''''''''' |  |  |  |  |  |
| In combination with paclitaxel and carboplatin, with or without bevacizumab, for the first-line treatment of patients with metastatic non-squamous NSCLC | 6 December 2018 |  | ''''' '''''''''' ''''''''''''' |  | March 2019 |  |  |  |

**Drug: avelumab [Bavencio, Merck Serono]**

| **Indication** | **FDA Approval** | **EMA approval (CHMP positive opinion)** | **TGA evaluation commenced** | **TGA approval** | **PBAC consideration** | | | **PBS listing** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First** | **Second** | **Third and subsequent** |
| Adults and paediatric patients 12 years and older with metastatic Merkel Cell Carcinoma (mMCC) | 23 March 2017 | 20 July 2017 | 3 January 2017 | 2 January 2018 | **July 2018** |  |  |  |

**Drug: durvalumab [Imfinzi, AstraZeneca]**

| **Indication** | **FDA Approval** | **EMA approval (CHMP positive opinion)** | **TGA evaluation commenced** | **TGA approval** | **PBAC consideration** | | | **PBS listing** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First** | **Second** | **Third and subsequent** |
| Treatment of patients with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy. | 16 February 2018 | 26 July 2018 | 29 September 2017 | 22 October 2018 | November 2018 |  |  |  |
| Treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. | 1 May 2017 |  | 1 February 2017 | 2 October 2018 |  |  |  |  |