Evaluate Vantage

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# Jemperli arrives just as accelerated approvals face a grilling

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With yesterday's green light for Glaxosmithkline's dostarlimab, some five months late owing to Covid-19 travel restrictions, the industry has its seventh US-approved anti-PD-(L)1 drug. The initial use, second-line mismatch repair-deficient endometrial cancer, is a small niche, and Merck & Co's Keytruda can already be given for second-line MSI-high/mismatch repair-deficient cancers – irrespective of tumour type. Immediate winners are Roche, whose Ventana MMR RxDx companion diagnostic is concurrently approved, and Anaptysbio, which scored a $20m milestone payment; Glaxo investors might now wonder how long it will be before dostarlimab, now branded Jemperli, generates the cash flow to cover the milestone. *Evaluate Pharma* sellside consensus sees Jemperli revenues rising from an anaemic $37m this year to $546m in 2026. The conditional approval came five days before a US adcom seeking to scrutinise the ongoing accelerated approvals of anti-PD-(L)1 drugs whose confirmatory studies have failed. As a just-published report from *Evaluate Vantage* reveals, this conditional pathway has found particular favour with anti-PD-(L)1 drugs, with Keytruda alone having 18 accelerated approvals to its name, 11 of which remain unconfirmed. Jemperli plus chemo is in Ruby, a controlled phase 3 endometrial cancer study that might be used to confirm yesterday's approval.

| US accelerated approvals of anti-PD-1/PD-L1 MAbs | | | |
|---|---|---|---|
| **Approval date** | **Therapy** | **Indication** | **Current approval status** |
| *Jemperli (Glaxosmithkline/Anaptysbio)* | | | |
| 22 Apr 2021 | Monotherapy | 2nd-line mismatch repair-deficient endometrial cancer | Not converted |
| *Libtayo (Sanofi-Regeneron)* | | | |
| 9 Feb 2021 | Monotherapy | 2nd-line or Hedgehog inhibitor-inappropriate basal cell carcinoma | Not converted |
| *Imfinzi (Astrazeneca)* | | | |
| 1 May 2017 | Monotherapy | 2nd-line urothelial carcinoma | Withdrawn |
| *Bavencio (Pfizer/Merck KGaA)* | | | |
| 9 May 2017 | Monotherapy | 2nd-line urothelial carcinoma | Converted to full approval |
| 23 Mar 2017 | Monotherapy | 2nd-line Merkel cell carcinoma | Not converted |
| *Tecentriq (Roche)* | | | |
| 8 Mar 2019 | Abraxane combo | 1st-line PD-L1 +ve (≥1%) triple-negative breast cancer | Not converted |
| 17 Apr 2017 | Monotherapy | 1st-line urothelial carcinoma (chemo ineligible; PD-L1 ≥5% if eligible for non-cisplatin) | Not converted; additional restriction |
| 18 May 2016 | Monotherapy | 2nd-line urothelial carcinoma | Withdrawn |
| *Opdivo (Bristol-Myers Squibb/Ono)* | | | |
| 16 Apr 2021 | Chemo combo | 1st-line gastric/GEJ/oesophageal adenocarcinoma | Not converted |

| US accelerated approvals of anti-PD-1/PD-L1 MAbs | | | |
|---|---|---|---|
| 10 Mar 2020 | Yervoy combo | 2nd-line liver cancer | Not converted |
| 17 Aug 2018 | Monotherapy | 3rd-line SCLC | Withdrawn |
| 10 Jul 2018 | Yervoy combo | 2nd-line MSI-H or mismatch repair-deficient colorectal cancer | Not converted |
| 22 Sep 2017 | Monotherapy | 2nd-line liver cancer | Not converted |
| 31 Jul 2017 | Monotherapy | 2nd-line MSI-H or mismatch repair-deficient colorectal cancer | Not converted |
| 2 Feb 2017 | Monotherapy | 2nd-line urothelial carcinoma | Not converted |
| 17 May 2016 | Monotherapy | 3rd-line classical Hodgkin lymphoma | Not converted |
| 23 Jan 2016 | Yervoy combo | 1st-line Braf-positive melanoma | Converted to full approval |
| 23 Jan 2016 | Monotherapy | 1st-line Braf-positive melanoma | Converted to full approval |
| 30 Sep 2015 | Yervoy combo | 1st-line Braf-W/T melanoma | Converted to full approval |
| 22 Dec 2014 | Monotherapy | 2nd-line melanoma | Converted to full approval |
| *Keytruda (Merck & Co)* | | | |
| 13 Nov 2020 | Chemo combo | 1st-line PD-L1 +ve (≥10%) triple-negative breast cancer | Not converted |
| 24 Jun 2020 | Monotherapy | Cutaneous squamous cell carcinoma not eligible for surgery/RT | Not converted |
| 16 Jun 2020 | Monotherapy | 2nd-line TMB-high (≥10mut/Mb) solid tumours | Not converted |
| 28 Apr 2020 | Monotherapy | 400mg q 6wk in all adult indications | Not converted |
| 17 Sep 2019 | Lenvima combo | 2nd-line, not MSI-H/dMMR, endometrial carcinoma | Not converted |
| 17 Jun 2019 | Monotherapy | 3rd-line SCLC | Withdrawn |
| 19 Dec 2018 | Monotherapy | 1st-line Merkel cell carcinoma | Not converted |
| 9 Nov 2018 | Monotherapy | 2nd-line liver cancer | Not converted |
| 13 Jun 2018 | Monotherapy | 3rd-line primary mediastinal large B-cell lymphoma | Converted to full approval |
| 12 Jun 2018 | Monotherapy | 2nd-line PD-L1 +ve (≥1%) cervical cancer | Not converted |
| 22 Sep 2017 | Monotherapy | 3nd-line PD-L1 +ve (≥1%) gastric/GEJ adenocarcinoma | Not converted |
| 23 May 2017 | Monotherapy | 2nd-line MSI-H or mismatch repair-deficient tumours | Not converted |
| 18 May 2017 | Monotherapy | 2nd-line or chemo-ineligible (1st-line) urothelial carcinoma | Not converted |
| 10 May 2017 | Chemo combo | 1st-line Alk & EGFR -ve non-squam NSCLC | Converted to full approval |
| 14 Mar 2017 | Monotherapy | 4th-line classical Hodgkin lymphoma | Converted to full approval |

| US accelerated approvals of anti-PD-1/PD-L1 MAbs | | | |
|---|---|---|---|
| 5 Aug 2016 | Monotherapy | 2nd-line head & neck cancer regardless of PD-L1 status | Converted to full approval |
| 2 Oct 2015 | Monotherapy | 2nd-line PD-L1 +ve (≥50%) NSCLC | Converted to full approval |
| 4 Sep 2014 | Monotherapy | 2nd-line melanoma | Converted to full approval |
| *Source: Evaluate Vantage & product labels.* | | | |