Evaluate Vantage

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By Jacob Plieth

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Spotlight on cervical cancer and perioperative settings

BY JACOB PLIETH

Formal approval for Keytruda looks to make life difficult for some anti-PD-(L)1 latecomers.

Welcome to the latest *Evaluate Vantage* update on developments in the PD-(L)1 inhibitor space. Recent weeks have been dominated by clinical and regulatory developments in two settings: second-line cervical cancer and perioperative treatment of non-small cell lung cancer.

The former saw Merck & Co's Keytruda convert its accelerated US approval into a full green light on the basis of the first-line Keynote-826 study. With a formally approved anti-PD-(L)1 drug on the market Agenus's accelerated filing for balstilimab in second-line cervical cancer became untenable, and the submission was pulled on October 22, less than two months before its US Pdufa date.

In neoadjuvant NSCLC, meanwhile, Bristol Myers Squibb celebrated the Opdivo/chemo combo Checkmate-816 study, which on November 8 added an event-free survival hit versus chemo alone to the positive pathological complete response rate readout toplined a year ago. Since EFS is the more robust of '816's two co-primary endpoints it could position Opdivo to become the first checkpoint-blocking MAb to be approved for neoadjuvant NSCLC, though of course it should be stressed that nothing has been disclosed yet about the magnitude of the EFS benefit.

This would be quite the turnaround for Bristol, which was edged out of the metastatic NSCLC race by Merck and has been struggling to catch up ever since. That said, early NSCLC treatment has become competitive.

On October 15 Roche scored US approval for Tecentriq in adjuvant NSCLC, based on the Impower-010 trial, which the FDA had not been due to rule on until December 1. There was no dream scenario of a broad label, however, the agency opting to follow the data and restrict approval to PD-L1-expressing patients with stage II-IIIA disease only; Impower-010 had included stage IB patients, where no benefit was seen, and PD-L1 non-expressers, in whom any benefit was likely illusory.

The stage is now set for Merck to reveal the results of Keynote-091, which tests Keytruda in an adjuvant NSCLC setting analogous to Impower-010. Keynote-091, also known as the Pearls study, had its primary completion date three months ago, according to clinicaltrials.gov, and Bernstein analysts expect readout at the start of 2022.

Before that, of course, another perioperative use will receive an FDA verdict: Keytruda's filing for high-risk stage II melanoma, based on Keynote-716, has a December 4 Pdufa date, and will determine whether Keytruda can broaden adjuvant melanoma use beyond the current lymph-involved (ie, stage III or later) setting of its own and Opdivo's labels. Meanwhile, the Merck drug was approved on November 18 for adjuvant renal cell carcinoma (Keynote-564), almost a month before its December 10 Pdufa date.

Selected cervical cancer trials

PD-(L)1 asset (company)	Study	Design	Result
Keytruda (Merck & Co)	Keynote-158 (cohort E)	Monotherapy (uncontrolled study)	Accelerated US approval for 2nd-line PD-L1 +ve (≥1%) cervical cancer; formalised after 1st-line approval
	Keynote-826	Chemo +/- Avastin combo (vs chemo)	Full US approval for 1st-line PD-L1 +ve (≥1%) cervical cancer (was positive in all-comers, too)
Balstilimab (Agenus)	Rapids	Monotherapy & anti-CTLA-4 combo (uncontrolled study)	Monotherapy filed for 2nd-line cervical cancer, with 16 Dec 2021 Pdufa date; filing pulled 22 Oct 2021
Libtayo (Sanofi/Regeneron)	Empower-Cervical-1	Monotherapy (vs chemo)	30 Jan 2022 Pdufa for 2nd-line cervical cancer
Bintrafusp alfa (Merck KGaA)	Intr@pid Cervical 017	Monotherapy (uncontrolled study)	2nd-line (checkpoint-naive) cervical cancer; ends Apr 2022
Imfinzi (Astrazeneca)	Calla	Chemo combo (vs chemo)	1st-line cervical cancer; data mid-2022

CERVICAL CANCER

Though Keytruda's cervical cancer approval was unexpected, having come four months ahead of schedule, the space was set to be shaken up as soon as positive Keynote-826 results were presented at Esmo in September.

Though this meant that Agenus was likely staring a balstilimab rejection in the face, the biotech group's stock still fell 22% when on October 22 it said was pulling the balstilimab filing based on FDA advice. Balstilimab monotherapy was never going to be a huge part of Agenus's business, but the group needed a single-agent approval in any setting just to get it to market, before focusing on more lucrative labels in combination with either of the group's two novel anti-CTLA-4 MAbs.

Balstilimab thus became the second PD-(L)1 latecomer, after Incyte/Macrogenics' retifanlimab, to be hit with US regulatory pushback. The FDA had issued retifanlimab's squamous carcinoma of the anal canal with a complete response letter in July, after an adcom voted in favour of rejection, citing data deficiencies.

Agenus claimed that the FDA's recommendation that it pull balstilimab's filing was based on a "technicality", and that such regulatory action was "unreasonable". In reality, however, the agency had acted in accordance with standard practice; with Keytruda on the market with a full, second-line approval, it was no longer appropriate for the agency to consider approving a rival on the basis of remission rates under an accelerated procedure.

Keytruda itself had had an accelerated second-line approval, but the randomised Keynote-826, though in the first-line setting, served as its confirmatory study. Positive '826 data backed a front-line label, granted on October 13, as well as formalising second-line use. The fact that Merck had generated no randomised second-line data appears to be the technicality here, but this matters little: front-line trials are often used to convert second-line accelerated approvals into full green lights.

In fact, the situation could become yet more complex, with Sanofi and Regeneron on September 28 revealing the filing for full approval of Libtayo for second-line cervical cancer. Notably this is based on survival data from a controlled trial, Empower-Cervical 1, where Libtayo showed an overall survival benefit versus chemo alone.

The FDA has set January 30 as the action date for this Libtayo filing. After that, by mid-2022 Astrazeneca is set to reveal the results of the Calla cervical cancer trial, which will show whether Imfinzi plus chemo will also challenge Keytruda on its new turf.

In cervical cancer it is also worth mentioning Merck KGaA's anti-PD-L1/TGF-ß fusion protein bintrafusp alfa, which remains in the uncontrolled Intr@pid Cervical 017 second-line study, due to end in April. However, hopes for this asset are very low after its failure in several studies, crowned by Glaxosmithkline's decision in September to terminate a licensing deal.

Anti-PD-1/PD-L1 MAb recent and upcoming US regulatory action

Regulatory action	Therapy	Indication	Supporting trials(s)
Libtayo (Sanofi-Regeneron)			
30 Jan 2022 Pdufa date	Monotherapy	2nd-line cervical cancer	Empower-Cervical-1
Tecentriq (Roche)			
Approved 15 Oct 2021	Monotherapy	Adjuvant PD-L1 +ve (≥1%) stage II-IIIA NSCLC	Impower-010 study
Opdivo (Bristol-Myers Squibb/Ono)			
28 May 2022 Pdufa date	Yervoy or chemo combo	1st-line oesophageal squamous cell carcinoma	Checkmate-648 study
19 Mar 2022 Pdufa date	Relatlimab combo	1st-line melanoma	Relativity-047 study
Keytruda (Merck & Co)			
28 Mar 2022 Pdufa date	Monotherapy	2nd-line MSI-H/dMMR endometrial monoRx	Keynote-158 study (cohorts D & K)
4 Dec 2021 Pdufa date	Monotherapy	Adjuvant high-risk stage II melanoma	Keynote-716 study
Approved 18 Nov 2021	Monotherapy	Adjuvant renal cell carcinoma	Keynote-564 study
Approved 13 Oct 2021	Chemo +/- Avastin combo	1st-line PD-L1 +ve (≥1%) cervical cancer	Keynote-826 study
Balstilimab (Agenus)			
Filing pulled 22 Oct 2021	Monotherapy	2nd-line cervical cancer	Rapids study
Sintilimab (Lilly/Innovent)			
xx Mar 2022 Pdufa date	Alimta combo	1st-line non-squam NSCLC	Orient-11 study
Penpulimab (Akeso/Sino)			
24 May 2021 filing	Monotherapy	3rd-line nasopharyngeal carcinoma	?
Tislelizumab (Beigene/Novartis)			
12 Jul 2022 Pdufa date	Novartis/Beigene	2nd-line oesophageal squamous cell carcinoma	Rationale-302 study

US APPROVAL DECISIONS

As well as Libtayo, also facing early 2022 FDA verdicts are Opdivo, in combination with Yervoy or chemo for front-line oesophageal squamous cell carcinoma, and in combination with the Lag3-blocking MAb relatlimab, for first-line melanoma; and Keytruda, for second-line MSI-high/dMMR endometrial cancer, a setting in which it would directly challenge Glaxosmithkline's Jemperli.

Should the Opdivo/relatlimab combo be approved (the action date is March 19) it would mark the first ever green light for the anti-Lag3 mechanism, and could give Bristol a new molecule to replace the relatively toxic Yervoy in Opdivo combinations. The first-line melanoma filing is based on the Relativity-047 study, whose full presentation at Asco suggested that relatlimab had a big safety advantage over Yervoy, with just a slight decrease in clinical benefit.

Relativity-047 showed median PFS of 10.1 months for relatlimab plus Opdivo, versus 4.6 months for Opdivo alone, with a 25% reduction in risk of progression overall (p=0.0055). On a cross-study basis Opdivo plus Yervoy yielded a slightly higher median PFS of 11.5 months in Checkmate-067, another front-line melanoma trial, while Opdivo monotherapy showed mPFS of 5.1 months in Checkmate-066.

In terms of adverse events, just 18.9% of Relativity-047 patients given the relatlimab combo had severe treatment-related adverse events, versus 59.0% in the Opdivo plus Yevoy cohort in Checkmate-067. Clearly, one question for the FDA will be whether a filing without overall survival data will be enough to secure approval.

Meanwhile, 2022 US first approval decisions comprise Lilly/Innovent's sintilimab in first-line non-squamous NSCLC, Akeso's penpulimab in third-line nasopharyngeal carcinoma, and Novartis/Beigene's tislelizumab in second-line oesophageal squamous cell carcinoma.

CHINA

Tislelizumab is already approved in China as Baizean, but the US submission is its first outside Beigene's home country. The verdict will be highly important for Novartis's oncology plans, given that in January the Swiss firm paid Beigene $650m up front for rights to tislelizumab in a move seen as an admission that Novartis's own anti-PD-1 asset, spartalizumab, was not up to the task, and was being deprioritised.

Perhaps the most important regulatory development in China, however, occurred on November 29, when Tracon/Alphamab/3D Medicines' envafolimab was approved in relapsed MSI-high/mismatch repair-deficient solid tumours. Not only was this envafolimab's first ever approval, it was the first green light for an anti-PD-(L)1 drug that is subcutaneously delivered – in 30 seconds in the physician's office, Tracon says.

Envafolimab is not a traditional MAb but rather a relatively lightweight humanised single-domain antibody with a mutant Fc region to extend its half-life. In the US it is in phase 3 (as a chemo combo for biliary tract cancer), as are two other SC MAbs, Pfizer's sasanlimab and Merck & Co's KN-555, a formulation of Keytruda.

Other regulatory developments in China since Evaluate Vantage's last report include Keytruda's approval for first-line oesophageal/gastroesophageal junction cancer, and Tecentriq's filing for adjuvant NSCLC, the same use in which it was approved in the US in October.

It has also been disclosed that a newcomer, Wuxi/Gloriabio's zimberelimab, was approved in China at the end of August for third-line classical Hodgkin's lymphoma, a setting with four other local anti-PD-(L)1 incumbents. Zimberelimab is notable for being in US development by Arcus, a company with ties to Gilead, under an ex-China deal struck in August 2017.

Anti-PD-1/PD-L1 MAb recent and upcoming regulatory action in China

Regulatory catalyst	Therapy	Indication	Supporting trials(s)
Envafolimab (ASC22/KN035; Tracon/Alphamab/3D)			
Approved 29 Nov 2021	Monotherapy	2nd-line MSI-H or mismatch repair-deficient tumours	NCT03667170 study
Zimberelimab (Wuxi/Gloriabio)			
Approved 30 Aug 2021	Monotherapy	3rd-line classical Hodgkin's lymphoma	NCT03655483 study
Annik/penpulimab (Akeso)			
Approval (currently filed)	Monotherapy	3rd-line nasopharyngeal carcinoma	?
Approval (currently filed)	Chemo combo	1st-line squamous NSCLC	?
Baizean/tislelizumab (Beigene)			
Approval (currently filed)	Monotherapy	2nd-line oesophageal squamous cell carcinoma	Rationale-302 study
Approval (currently filed)	Monotherapy	2nd-line MSI-H/dMMR solid tumours	NCT03736889 study
Tyvyt/sintilimab (Innovent Biologics)			
Approval (currently filed)	Monotherapy	2nd-line squamous NSCLC	Orient-3 study
Tuoyi/JS001/toripalimab (Shanghai Junshi Bioscience; lic to Astrazeneca for China, and to Coherus for US)			
Approval (currently filed)	Chemo combo	1st-line oesophageal squamous cell carcinoma	Jupiter-06 study
Tecentriq (Chugai (Roche))			
Approval (currently filed)	Monotherapy	Adjuvant PD-L1 +ve (≥1%) stage II-IIIA NSCLC	Impower-010 study
Keytruda (Merck & Co/Taiho)			
Approved 7 Sep 2021	Chemo combo	1st-line oesophageal/GEJ carcinoma	Keynote-590 trial
Opdivo (Bristol-Myers Squibb/Ono)			
Approved 31 Aug 2021	Chemo combo	1st-line gastric/GEJ/oesophageal adenocarcinoma	Checkmate-649 study
HLX10 (Henlius (Fosun))			
Approval (currently filed)	Monotherapy	MSI-high solid tumours?	?
Envafolimab (ASC22/KN035; Tracon/Alphamab)			
Approval (currently filed)	Monotherapy	MSI-high solid tumours	?

Anti-PD-1/PD-L1 MAb recent and pending approvals in Japan

Filing date	Therapy	Indication	Supporting trial(s)
Tecentriq (Chugai (Roche))			
Filed 6 Jul 2021	Monotherapy	Adjuvant PD-L1 +ve (≥1%) NSCLC	Impower-010 study
Opdivo (Bristol-Myers Squibb/Ono)			
Filed 14 Apr 2021	Monotherapy	Cancer of unknown primary	NivoCUP study
Filed 31 Mar 2021	Monotherapy	Adjuvant high-risk urothelial carcinoma	Checkmate-274 study
Filed 18 Feb 2021	Monotherapy	Adjuvant oesophageal/GEJ cancer	Checkmate-577 study
Filed 10 Dec 2020	Chemo (or Yervoy?) combo	1st-line gastric cancer	Checkmate-649 + Attraction-4 studies
Keytruda (Merck & Co/Taiho)			
Approved 30 Nov 2021	Chemo combo	1st-line oesophageal/GEJ carcinoma	Keynote-590 study

EU

Opdivo, whose latest China approval was as a chemo combo in first-line gastric/gastroesophageal junction/oesophageal adenocarcinoma, added this same indication to its EU approved uses on October 21. This was backed by the Checkmate-649 study, but interestingly the EU restricted approval to PD-L1 ≥5% expressers, while the FDA cleared the drug in all-comers.

The study, in Her2-negative patients, read out positively for overall survival in ≥5% PD-L1 expressers as well as in all randomised subjects, but a concern was that the former drove most of the benefit in the latter. Either way, the prescribing picture in this cancer type has become extremely complicated. And Keytruda, whose own chemo combo is approved in the US and EU for front-line oesophageal/gastroesophageal junction carcinoma, features a similar dichotomy: the FDA greenlit it in all-comers while the EMA restricted it to PD-L1 ≥10% expressing Her2-negatives.

October's other EMA approval was for Keytruda in first-line, PD-L1 ≥10% expressing triple-negative breast cancer. A month later the Merck drug saw the formalisation of two more positive CHMP opinions, in first-line renal cell carcinoma and second-line endometrial carcinoma, both as part of a combo with Lenvima.

And Opdivdo's relatlimab combo is also awaiting EU approval, for front-line melanoma, as is Tecentriq monotherapy for adjuvant treatment of PD-L1-positive NSCLC.

Anti-PD-1/PD-L1 MAb recent and upcoming EU regulatory action

Regulatory status	Therapy	Indication	Supporting trials(s)
Tecentriq (Roche)			
Filed	Monotherapy	Adjuvant PD-L1 +ve (≥1%) stage II-IIIA NSCLC	Impower-010 study
Opdivo (Bristol-Myers Squibb/Ono)			
Filed	Relatlimab combo	1st-line melanoma	Relativity-047 study
Filed	Yervoy or chemo combo	1st-line oesophageal squamous cell carcinoma	Checkmate-648 study
21 Oct 2021	Chemo combo	1st-line Her2-ve PD-L1≥5% gastric/GEJ/oesophageal adenocarcinoma	Checkmate-649 study
Keytruda (Merck & Co)			
Approved 29 Nov 2021	Lenvima combo	1st-line renal cell carcinoma	Keynote-581/Clear study
Approved 29 Nov 2021	Lenvima combo	2nd-line endometrial carcinoma	Keynote-775 study
Approved 22 Oct 2021	Chemo combo	1st-line PD-L1 +ve (≥10%) triple-negative breast cancer	Keynote-355 study

CLINICAL DATA

Among clinical successes over the past three months perhaps the most unexpected was the result of Astrazeneca's Himalaya trial in front-line liver cancer. Not only had this study been delayed, it featured Imfinzi as well as an Imfinzi/tremelimumab combo, and the latter appeared to perform better than the former.

Until the combo's unexpected success in the NSCLC study Poseidon, which also included chemo, tremelimumab had run up a dismal record of failures, and Astra seemed largely to have deprioritised it.

Though full data from Himalaya have not been made public, the success appears to be due at least partly to Stride, a novel dosing regimen that comprises just a single 300mg priming dose of treme together with Imfinzi, followed by Imfinzi alone, and could avoid treme's toxicities.

Still, with Roche's Tecentriq plus Avastin already available, on the basis of Imbrave-150, first-line liver cancer is no longer the immuno-oncology white space it once was. More recently a Tecentriq combo with Exelixis's Cabometyx failed the Cosmic-312 trial, however. In China Innovent's Tyvyt is approved in combination with an Avastin biosimilar called Bevasda.

Keytruda, meanwhile, retains a second-line US label but its Lenvima combo got an FDA complete response letter for first-line use because, after Tecentriq/Avastin's approval, the uncontrolled Keynote-524 trial no longer gave sufficient backing. Opdivo has already failed in first-line liver cancer, as monotherapy in Checkmate-459 – a result that prompted this year's withdrawal of Opdivo's second-line label; a Yervoy combo remains available second line.

The next relevant liver cancer readout should come later this year from a Chinese study of Jiangsu Hengrui's camrelizumab, though the big threats in terms of Western datasets are Beigene's Rationale-301 trial of tislelizumab, and Merck & Co/Eisai's Leap-002 study of Keytruda plus Lenvima. Both have primary completion dates next May.

Imfinzi scored a separate unexpected success in October in Topaz-1, a pivotal first-line cholangiocarcinoma study. Treating this rare malignancy, also known as bile duct cancer, has only recently seen progress, but this came thanks to targeted treatments like Incyte's Pemazyre and Bridgebio's Truseltiq. Meanwhile, immuno-oncology has fired blanks, including an early, academic-sponsored trial of Bristol Myers Squibb's Opdivo yielding "modest" efficacy, and bintrafusp alfa failing to hit a remission rate threshold.

Astra's success should be of interest to Merck & Co, whose Keynote-966 study of Keytruda has a similar design to Topaz-1. Roche is running Imbrave-151, combining Tecentriq plus chemo with or without Avastin in first-line disease, but this did not appear on the Swiss group's latest summary of clinical trials.

(NEO)ADJUVANT

All that said, given recent approvals and upcoming decisions in adjuvant settings, investor attention will remain focused on such perioperative treatment. These offer companies the prospect of reinvigorating sales of some immuno-oncology franchises, and they could usher in a period of renewed growth.

Merck will already be hoping to make up ground lost to Roche in adjuvant NSCLC, with next year's expected readout of Keynote-091, a trial broadly analogous to Impower-010. For its part, Roche will look to Impower-030, set to yield data next year, to stay ahead of Merck; this study tests Tecentriq plus chemo in neoadjuvant stage II-IIIB NSCLC, and results will clearly be held up against those of Opdivo in Checkmate-816.

Also next year, Tecentriq will yield data from Immotion-010, an adjuvant renal cancer trial rivalling Keytruda's recent approval, and Imbrave-050, which will seek to extend Tecentriq's liver cancer presence from the front line to adjuvant use.

A final notable duel exists in adjuvant head and neck cancer, where Tecentriq's Imvoke-010 trial and Keytruda's Keynote-412 are to read out next year. In the metastatic head and neck cancer setting Opdivo has a second-line approval, while Keytruda has a front-line label, either as monotherapy in PD-L1 ≥1% expressers, or as a chemo combo in all-comers.

But success is not assured, as the Merck drug strangely failed Keynote-040, a second-line study that was potentially confirmatory for an earlier second-line accelerated approval. Opdivo, Imfinzi and Bavencio have also failed first-line head and neck cancer trials.

Evaluate Vantage will bring you news and analysis of future events, as they happen via our daily alert and in subsequent periodic updates.

Selected adjuvant & neoadjuvant studies

Study	Indication/setting	Outcome	Note
Tecentriq (Roche)			
Impower-030	Chemo combo, neoadjuvant stage II-IIIB NSCLC	Readout in 2022	Compare data vs Checkmate-816
Immotion-010	MonoRx, adjuvant renal cell carcinoma	Readout in 2022	Compare data vs Keynote-564
Imbrave-050	Avastin combo, adjuvant liver cancer	Readout in 2022	–
Imvoke-010	Adjuvant head & neck cancer	Readout in 2022	Compare data vs Keynote-412
Impassion-030	Chemo combo & monoRx, adjuvant triple-negative breast cancer	Ends Aug 2023	Compare data vs Keynote-522
Impassion-031	Abraxane combo & monoRx, neoadjuvant & adjuvant triple-negative breast cancer	Filed in EU Q4 2020; filing pulled Aug 2021	
Impower-010	MonoRx, adjuvant stage IB-IIIA NSCLC	US approval 15 Oct 2021 for PD-L1 +ve (≥1%) stage II-IIIA disease	Also filed in EU, Japan & China for PD-L1+ve disease
Opdivo (Bristol Myers Squibb/Ono)			
Checkmate-816	MonoRx or Yervoy + chemo combo, neoadjuvant stage IB-IIIA NSCLC	Positive for pCR & EFS	Imminent US filing?
Checkmate-274	MonoRx, adjuvant high-risk musle-invasive urothelial carcinoma	US approval 20 Aug 2021 for adjuvant high-risk disease	Also filed in Japan
Checkmate-577	MonoRx, adjuvant oesophageal/GEJ cancer	US approval 20 May 2021	Also approved in EU & filed in Japan
Checkmate-238	MonoRx, adjuvant melanoma with lymph node involement (so stage III+) or metastatic	US approval 20 Dec 2017	Also approved in EU & Japan
Keytruda (Merck & Co)			
Keynote-412	Adjuvant head & neck cancer	Readout in 2022	Compare data vs Imvoke-010
Keynote-091	MonoRx, adjuvant stage IB-IIIA NSCLC	Readout in early 2022	Analogous to Impower-010
Keynote-716	MonoRx, adjuvant high-risk stage II melanoma	4 Dec 2021 US Pdufa date	–
Keynote-564	MonoRx, adjuvant renal cell carcinoma	US approval 18 Nov 2021	Pdufa date had been 10 Dec 2021
Keynote-522	Chemo combo & monoRx, neoadjuvant & adjuvant triple-negative breast cancer	US approval 27 Jul 2021	Compare data vs Impower-030 & 031
Keynote-054	MonoRx, adjuvant melanoma with lymph node involement (so stage III+)	US approval 19 Feb 2019	Also approved in EU & Japan

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