Evaluate Vantage

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# Immuno-oncology spotlight falls on cervical cancer

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

Welcome to the second in a series of periodic *Evaluate Vantage* updates 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, leading Agenus to pull its submission for balstilimab less than two months before its 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. This could position Opdivo to become the first checkpoint-blocking MAb to be approved for neoadjuvant NSCLC – quite the turnaround for Bristol.

This update details further clinical and regulatory catalysts, plus developments that took place in September-November, including:

- Key upcoming catalysts in cervical cancer.
- Other recent US approvals and upcoming Pdufa dates.
- Recent approvals in China, including two first-time approvals.
- Regulatory state of play in Japan.
- Upcoming regulatory catalysts in the EU.
- Clinical successes and upcoming catalysts, including in liver and bile duct cancers.
- Analysis of upcoming clinical trial readouts in neo/adjuvant trials including NSCLC, melanoma, renal, kidney, breast, stomach and other cancers.

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