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Physician Views – Taking a Post-ASCO Pulse on the PD-L1 Biomarker Debate in Non-Small-Cell Lung Cancer

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Abstracts

The data presented at this year's ASCO annual meeting, which has subsequently fuelled the most debate, is likely that from Bristol-Myers Squibb's Checkmate-057 study, assessing its PD-1 inhibitor Opdivo for the treatment of second-line non-squamous non-small-cell lung cancer (NSCLC).

Results from the Checkmate-057 study illustrated that Opdivo was associated with a 27-percent reduction in the risk of progression or death compared to docetaxel, positioning Bristol-Myers Squibb's product as the first PD-1 inhibitor to show a significant improvement in overall survival in a Phase III trial in non-squamous NSCLC compared with the current standard of care.

A subsequent analysis of survival based on PD-L1 expression demonstrated that this benefit was driven, however, by those patients who had pre-specified PD-L1 expression levels of 10 percent or more. Investors sent Bristol-Myers Squibb's share price down as a result, given a consensus-supported view that Opdivo was likely to work in all non-squamous NSCLC patients, irrespective of PD-L1 status (FirstWord Lists: Best selling cancer drugs - 2014 and 2020).

An earlier study – Checkmate-017, used to support approval of Opdivo in second-line squamous NSCLC – had supported this view and appeared to validate Bristol-Myers Squibb's status as a 'reluctant adopter of PD-L1 testing' in the advanced lung cancer indication, noted Bernstein analyst Tim Anderson. The consequences of these 'unexpected' data from Checkmate-057 are a potential opportunity for rival players Roche and Merck & Co. to be more competitive in second-line lung cancer and the strength of Bristol-Myers Squibb's biomarker capabilities (ViewPoints: Opdivo

disappoints in lung cancer – Bristol-Myers Squibb's pain could be Merck & Co., Roche's gain).

Clinical and regulatory implications stemming from the PD-L1 as a biomarker debate will increasingly converge in the coming months, based on submission of Opdivo for approval in non-squamous NSCLC based on the Checkmate-057 data, confirmation that Merck's Keytruda has been accepted for priority review (based on data in PD-L1 positive patients, but with management taking up the potential for a broad label) and with Roche expected to file its PD-L1 inhibitor in advanced lung cancer in late 2015/early 2016.

With these factors in mind, Anderson wrote in a note to investors this week 'it seems to us that this matter will be headed to an FDA advisory committee at some point soon. The agency would want to discuss the role of PD-L1 testing both in product labels and in clinical practice, within the limits of the clinical trial data it currently has. Clearly, the biomarker situation is fluid, but increasingly there seems to be concordance among different companies' findings.'

On the back of the Checkmate-057 data presented at ASCO, and fuelled by increasing debate around the validity of PD-L1 as a biomarker in the sizeable market for advanced NSCLC, we are polling US and EU5 oncologists this week with the following questions…

> Based on data from the Checkmate-057 study presented at ASCO, do you think Opdivo should be approved with a broad label for the treatment of all second-line non-squamous NSCLC patients – i.e. PD-L1 expressers and non-expressers?
>
> Assuming a broad label is approved, how would you expect to use Opdivo in PD-L1 non-expressing patients?
>
> If competing PD-1/PD-L1 inhibitors reach the market for the treatment of second-line NSCLC with labelling restricted to PD-L1 expressers (given selection by biomarker for pivotal stage study enrolment), would you likely use these products in non-expressing patients also?
>
> Do you think that approval of subsequent therapies labelled specifically for PD-L1 expressing, second-line NSCLC patients – and launched with companion diagnostics – would support more proactive patient stratification on your part and the use of these treatments more frequently in PD-L1 expressing patients (i.e.

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do you expect more stratification of this indication over time)?

Based on you reading of current data, how confident are you in the use of PD-L1 as an effective biomarker in lung cancer? Confused with current discussion around PD-L1

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