MARKET REPORT

Physician Views: Reaction to Bristol-Myers Squibb's Opdivo data in non-small-cell lung cancer

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Scope

Studies of Bristol-Myers Squibb's PD-1 inhibitor nivolumab in non-small-cell lung cancer (NSCLC) have been watched closely by investors, analysts and the oncology community, given both the high level of unmet need in this indication and the size of the commercial opportunity.

Nivolumab, which is branded as Opdivo, is forecast to generate global sales of around $6 billion by the end of the decade, with a significant proportion attributed to lung cancer.

Little surprise then, perhaps, that Bristol-Myers Squibb's share price jumped some 9 percent last week when positive data from the Phase II Checkmate-063 study, assessing Opdivo in third-line squamous NSCLC patients, were unveiled (ViewPoints: Investors respond in kind to impressive data for Bristol-Myers Squibb NSCLC immunotherapy).

Checkmate-063 recruited 117 patients, each of whom had failed two prior lines of therapy. They were dosed 3mg/kg of Opdivo every two weeks until progression with the study producing an overall response rate (ORR) of 15 percent and a one-year survival rate of 41 percent.

Contextualising the Checkmate-063 data nevertheless remains challenging, given both the single-arm design of the study and a lack of historical data. In a note to investors, ISI analyst Mark Schoenebaum suggested that the "numbers to beat" for Opdivo in this setting were an estimated ORR in the mid-single digits and a one-year survival rate of around 20 percent.

However, Sanford C. Bernstein analyst Tim Anderson was slightly more cautious towards the historical benchmarking for the all important one-year survival rate, noting that a 21 percent rate (or 18 percent for squamous patients) cited by Bristol-Myers Squibb stemmed from a database comprising only Medicare patients aged 66 years or older. This may be an older patient population than that enrolled in Checkmate-063, added Anderson.

Benchmarking Opdivo's impressive looking overall survival rate is particularly important given the nature of these immunotherapies, which are not effective in all patients, but in those who are responsive can result in long, durable responses. This characteristic raises the prospect, particularly in European markets perhaps, that some stratification of patients may be encouraged before usage is approved. Key opinion leaders recently interviewed by FirstWord's Therapy Trends team have alluded to this occurring.

One key question stemming from the Checkmate-063 data is whether it alone will be sufficient to support approval in the third-line squamous indication, or whether the FDA will also choose to assess interim data from the ongoing Checkmate-017 study, which is comparing Opdivo to Taxotere in second-line squamous NSCLC patients. Squamous patients are not only more difficult to treat, but there are also no approved therapies in the third-line setting. Furthermore, around 65 percent of the patients enrolled in Checkmate-063 had been heavily pre-treated, previously receiving four or more lines of therapy.

The other key question is whether data from Checkmate-063 has any read-across to Checkmate-017. In a Phase I study, Opdivo was shown to demonstrate a dose-dependent one-year survival rate among squamous and non-squamous patients of between 42 percent and 56 percent, while Taxotere has previously demonstrated one-year survival rates of between 34 percent and 36 percent in the second-line setting.

Puchase Reasons

In response to the Checkpoint-063 data, we are polling US and EU5-based oncologists with the following questions...

Based on the Phase II data from Checkpoint-063 (third-line squamous NSCLC), how confident are you that nivolumab will produce data sufficient to drive significant usage in second-line squamous NSCLC patients? Nivolumab is currently being assessed head-to-head versus Taxotere in a Phase III study in this indication (note: Taxotere has previously demonstrated one-year survival rates of between 34 percent and 36 percent in the second-line setting).Additional Details**Publisher** : FirstWord Pharma
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