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Physician Views: The PD-1 inhibitor class lands – how do US oncologists expect to initially use Merck & Co.'s Keytruda?

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Abstracts

As many were expecting, approval of Merck & Co.'s pembrolizumab – now branded as Keytruda – came earlier than expected, and was confirmed on Thursday ahead of October's PDUFA date.

Approved as the first PD-1 inhibitor in the US market, Thursday's announcement also confirmed that Keytruda will command an annualised price of around $150,000 per patient (or $12,500 per month). This is broadly in line with buy-side expectations, noted International Strategy & Investment analyst Mark Schoenebaum, but at a premium to some analyst forecasts (25 percent above the price envisioned by analysts at Leerink Swann, for example).

Some questions remain unanswered, however. Primarily whether Keytruda will be used outside of its approved indication – the treatment of unresectable or metastatic melanoma and disease progression following Yervoy (ipilimumab) and, if BRAF V600-mutation positive, a BRAF inhibitor (see also Physician Views Poll Results – Oncologists suggest Mekinist/Tafinlar combination will experience notable growth in melanoma over next 12 months

Most analysts expect initial usage of Keytruda to occur in line with its narrow label, which could generate sales of up to $140 million in the US, note analysts at Leerink. Bernstein analyst Tim Anderson has maintained for some time, however, that given the excitement and enthusiasm for PD-1/PD-L1 inhibitors, off-label use – either in first-line patients as a monotherapy or even possibly in combination with Bristol-Myers Squibb's Yervoy – could be underestimated. A previous poll of oncologists run by FirstWord indicates that Anderson may be correct in this assertion.

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To further assess the potential usage of Keytruda over the next six to eight months (the approximate head-start it holds over Bristol-Myers Squibb's nivolumab in melanoma) the first part of this week's Physician Views poll will be asking US oncologists.

> What percentage of total melanoma patients they estimate are eligible for treatment with Keytruda (pembrolizumab) based on its approved use?
>
> To what percentage of first-line melanoma patients they anticipate prescribing Keytruda (pembrolizumab) as a monotherapy (in an off-label capacity) six to nine months after launch?
>
> To what percentage of first-line melanoma patients they anticipate prescribing a combination of Keytruda (pembrolizumab) and Yervoy (ipilimumab) - in an off-label capacity - six to nine months after launch?
>
> To what percentage of first-line patients they anticipate prescribing Keytruda (pembrolizumab) in an off-label capacity six to nine months after launch (encompassing the decision to forego BRAF V600 testing or prescribing Keytruda as a monotherapy irrespective of BRAF V600 status)?
>
> How significant a role compendia listing will play in driving potential off-label use of Keytruda (pembrolizumab) in first and second-line patients

Given the significance of this approval – the PD-1/PD-L1 inhibitors are expected to spearhead evolution of a multi-billion dollar market over the next decade – this Physician Views poll contains a second component that provides oncologist assessment of Keytruda's label and the role that the FDA is playing to expedite approval of breakthrough cancer products.

A number of analysts were quick on Thursday to commend both Merck and the FDA for the rapid execution shown in bringing Keytruda from the clinic to the market in such a short period of time; approval occurred just 3.5 years after the first clinical study was initiated. Specifically, the second part of this week's Physician Views poll will ask.

> Based on a reported annualised cost of $150,000 per patient per year, how does the price of Keytruda compare to their pre-approval expectations for the PD-1/PD-1L inhibitor class?

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Based on the approved label for Keytruda (pembrolizumab), how they assess the safety profile of the product?

Whether they will have any reluctance in using Keytruda given that approval is based on tumour response rate and durability of response rate (and with continued approval being conditional on confirmatory clinical benefit data)?

What level of off-label use they anticipate in other tumour types where Keytruda is being studied (i.e. non-small-cell lung cancer) prior to full approval?

Taking into consideration the speed at which Keytruda gained regulatory clearance, how they assess the current role of the FDA in its regulation/approval of oncology products?

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