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Physician Views: Pfizer delivered regulatory promise with Ibrance, can it deliver a strong launch?

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Abstracts

While much of the focus at Pfizer continues to be sharpened on M&A activity, recent approval of Ibrance (palbociclib) for the first-line treatment of ER+/HER2- breast cancer may have been overlooked in some quarters.

It should not be. Ibrance not only represents one of the most commercially promising drugs to emerge from Pfizer's R&D pipeline in recent years, but approval on the strength of Phase II data, and some two months ahead of its April PDUFA date, has vindicated the company's bullish stance on delivering the drug to market (ViewPoints: Pfizer sets out – earlier than expected – to show value of pipeline via Ibrance).

Investors had run hot and cold on the prospect of Pfizer successfully gaining approval for Ibrance ahead of Phase III data (with the relevant PALOMA-2 study expected to complete by year-end) and when FirstWord polled oncologists back in August, respondents were split fairly evenly as to whether they thought Phase II results were sufficient to support regulatory clearance.

A key question is whether this reticence will curb uptake of Ibrance until Phase III data – and a demonstrated overall survival benefit – are available. Positively for Pfizer and breast cancer patients, key opinion leaders (KOLs) interviewed by FirstWord's Therapy Trends team on a number of occasions during the second half of last year grew increasingly upbeat about the chances of approval and their usage of the drug. A number of KOLs who had used Ibrance first hand were extremely positive about the product and the progression-free survival benefit (PFS) when used in combination with the aromatase inhibitor letrozole versus letrozole alone (20.2 month versus 10.2 months).

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Indeed, a consistent message from KOLs was whether FDA labelling would be vague enough to either utilise the Ibrance/letrozole combination in pre-treated metastatic patients or with an alternative aromatase inhibitor to letrozole in patents already treated with this drug in the adjuvant setting.

With approval now secured in the US and with the FDA having given Ibrance considerable regulatory backing (the drug was both granted breakthrough therapy and priority review status), we are polling US-based oncologists to ascertain how they expect to use the drug over the next 12 months during its initial launch phase. Specifically we are asking them…

How clinically meaningful do you perceive the PFS data for Ibrance to be in the first-line ER+/HER2- breast cancer indication?

Not at all meaningful

Slightly meaningful

Moderately meaningful

Very meaningful

Extremely meaningful

What is the likelihood of you attempting to utilise Ibrance (in combination with letrozole) in pre-treated (with an aromatase inhibitor) ER+/HER2- breast cancer patients prior to progression to chemotherapy over the next 12 months?

Not at all likely

Slightly likely

Moderately likely

Very likely

Extremely likely

What is the likelihood of you attempting to utilise Ibrance in combination with an

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alternative aromatase inhibitor in metastatic ER+/HER2- breast cancer patients who have already received treatment with letrozole in the adjuvant setting?

Not at all likely

Slightly likely

Moderately likely

Very likely

Extremely likely

Will the fact that the FDA granted expedited approval of Ibrance – through both the Breakthrough Therapy designation and Priority Review programmes – on the strength of Phase II data and two months ahead of its scheduled PDUFA date, have any meaningful impact on your usage of the drug versus a scenario whereby the product had been approved on the strength of pivotal stage data over a typical review period?

Yes – significantly more likely to use

Yes – moderately more likely to use

Yes – marginally more likely to use

No – my usage of the product will be unchanged

No – marginally less likely to use until Phase III data/demonstrated overall survival benefit is available

No – moderately less likely to use until Phase III data/demonstrated overall survival benefit is available

No – significantly less likely to use until Phase III data/demonstrated overall survival benefit is available

What percentage of first-line ER+/HER2- breast cancer patients would you expect to be prescribing Ibrance to 12 months post-launch?

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