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Physician Views: When and where do oncologists see palbociclib fitting into the ER+, HER2- breast cancer landscape?

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Abstracts

Analysts believe palbociclib is likely headed for an accelerated approval to treat a subset of breast cancer, which would give Pfizer a big leg up over competitors like Eli Lilly and Novartis with less advanced compounds in the CDK 4/6 inhibitor class.

Expectations for palbociclib were flying high in 2012 when Pfizer reported preliminary results from the Phase II PALOMA-1 trial showing the drug improved progression-free survival (PFS) by 18.6 months when added to Femara in postmenopausal women with oestrogen receptor (ER) positive, HER2-negative locally advanced or metastatic breast cancer (26.1 months versus 7.5 months). In fact, the FDA found the early data compelling enough to grant the product breakthrough therapy status last year.

However, the waters were muddied this spring by updated PALOMA-1 results that were seen as a disappointment by many on the Street. Specifically, palbociclib's PFS advantage had narrowed considerably to only 10 months, while an interim look at the secondary endpoint of overall survival (OS) showed the compound failed to achieve significance (37.5 months for the combination versus 33.3 months for Femara alone).

The lack of improvement on the OS endpoint appeared to catch many by surprise given palbociclib's particular robust impact on PFS. Nonetheless, after discussions with the FDA, Pfizer announced its intentions to submit a filing for palbociclib this quarter, though the company declined to share whether the decision was being driven by itself or the agency. Either way, Pfizer followed through on the plan andcompleted submission of the application earlier this month.

Jefferies analyst Jeffrey Holford suggested the strong PFS data and 'consistent

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improvement across other efficacy measures,' along with a relatively clean safety profile strengthen Pfizer's case for approval of palbociclib.

Approval based on PALOMA-1 alone would be an important achievement for Pfizer. Analysts predict marketing applications for its closest competitors, such as Eli Lilly's bemaciclib and Novartis' LEE011, will not be ready before at least 2016, meaning the sooner palbociclib is approved the stronger foothold it will have.

Thus, to better understand the likelihood of an accelerated approval of palbociclib, as well as how it might fit into the commercial setting, FirstWord is this week polling US-based oncologists. Specifically we are asking them.

> Given the small size (165 patients) and open-label design of the Phase II PALOMA-1 study, combined with the non-significant difference on overall survival at the interim update this spring, are the data showing palbociclib improved progression-free survival by 10 months in ER+, HER2- breast cancer patients sufficient to support an accelerated approval in this setting?
>
> Based on previous experiences in this setting, such as iniparib (Phase II data failed to translate to OS benefit in Phase III) and Avastin (accelerated approval based on PFS later revoked when it did not improve OS), would the FDA be right to wait for data confirming a survival advantage before approving palbociclib in this setting?
>
> Based on the data available for various CDK 4/6 inhibitors (eg, Eli Lilly's bemaciclib and Novartis' LEE011), how does Pfizer's palbociclib appear to stack up and what impact will this have on how much use it receives?
>
> Does use of Femara (letrozole) in the adjuvant setting make the results of PALOMA-1 difficult to interpret?
>
> What percentage of front-line patients with ER+, HER2- breast cancer do you expect to use palbociclib in 12 months from now?

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