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Physician Views: What does the future hold for new EGFR targeting NSCLC therapies?

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Abstracts

Propelled via momentum from new data presented at the ASCO annual meeting, AstraZeneca's AZD-9291 and Clovis Oncology's CO-1686 look poised to advance the treatment paradigm for EGFR-positive non-small-cell lung cancer (NCSLC) patients over the next 12 to 18 months.

Both products are initially being developed for patients who have seen their disease progress after treatment with currently available targeted therapies, by selection of those EGFR-positive patients with the T790m mutation – which causes approximately half of the cases of acquired resistance to therapy with Tarceva (erlotinib; Roche), Iressa (gefitinib; AstraZeneca) and Gilotrif (afatinib; Boehringer Ingelheim).

The key question being asked post-ASCO is which product – AZD-9291 or CO-1686 – is superior? It is probably too soon to provide a definitive answer, but initial assessment of both products has focused primarily on side-effect profiles, given that in patients with the T790m-positive mutation AZD-9291 and CO-1686 have demonstrated comparable response rates.

While side effects for both products based on currently available data are treatable, a notable point of discussion around ASCO was increased risk of developing hyperglycaemia with CO-1686, which has caused some patients receiving the drug to also be treated with diabetes therapies. In addition, CO-1686 shows QTc prolongation, while AZD-9291 appears to have a worse side-effect profile in terms of rash and gastrointestinal events (thought to be due to slightly more pronounced off-target activity in hitting wild-type T790m negative) and also demonstrates more interstitial lung disease (ILD).

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See Friday Five – 5 questions raised this week in pharma (ASCO edition) and ViewPoints: AstraZeneca senses chance to leapfrog Clovis in NSCLC race.

A second point under discussion is the possibility of eventual use for these two drugs as a first-line targeted therapy (i.e. instead of Tarceva, Iressa or Gilotrif). While AstraZeneca has been more cautious in this approach and has only recently announced that it will initiate a Phase III study (although conversely two-thirds of the company's peak forecast sales of $3 billion for AZD09291 are attached to first-line usage), Clovis is set to begin head-to-head studies for CO-1686 versus Tarceva in the current quarter. It is assumed that data from the TIGER1 study – a randomised Phase II/III registration study of CO-1686 versus Tarceva in newly diagnosed EGFR mutant patients (not screened for T790m-positive status – will be presented at next year's ASCO meeting.

To gain better physician insight on the potential future role of these two therapies, FirstWord is polling oncologists based in the US and EU5 with the following questions...

Based on currently available data, whether one of AZD-9291 or CO-1686 has a stronger overall clinical profile?

What is the potential opportunity for use of AZD-9291 and CO-1686 ahead of current EGFR therapies such as Tarceva based on current data?

What progression-free survival (PFS) benefit CO-1686 would have to demonstrate in the TIGER1 study to drive moderate switching into first-line targeted therapy patients?

Where in the treatment paradigm these T790m-positive targeting therapies are likely to be used most based on available data and physician enthusiasm?

Which product among the currently available EGFR inhibitors they expect to lose most market share at the expense of CO-1686 and/or AZD-9291?

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