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Scope

Much of the debate around cancer immunotherapy at the recent ASCO annual meeting focused on the commercial positioning of a new class of product – the PD-1/PD-L1 inhibitors – in second-line, non-small-cell lung cancer (Physician Views Poll Results – Oncologists give thumbs up for Bristol-Myers Squibb's Opdivo despite biomarker jitters and ViewPoints: Biomarker debate diffused by new US treatment guidelines for Opdivo in non-small-cell lung cancer).

Focus is rapidly switching, however, to the opportunity for these products – either as monotherapies or in combinations – in the much larger first-line NSCLC market. This indication could be as much as twice as large as the second-line market, suggests ISI Evercore analyst Mark Schoenebaum, and represents an intriguing showdown given that different drug manufacturers are implementing markedly different development strategies.

Potentially disruptive Phase I/II data in 30 first-line patients were unveiled by Roche at ASCO, demonstrating that the combination of its PD-L1 inhibitor atezolizumab with chemotherapy produced overall response rates above 60 percent. Not only does this data represent a significant benefit over chemotherapy alone (typical response rates of between 20 percent and 30 percent), but the combination demonstrated a similar side-effect profile to that of chemotherapy and exhibited a strong activity irrespective of PD-L1 status.

These data, while needing to be replicated in larger Phase III studies, are significant given that a prominent narrative related to the emergence of immunotherapy has been an assumption that availability of new treatments could remove chemotherapy from the treatment paradigm. Indeed, Bristol-Myers Squibb – which looks poised to lead the market in second-line NSCLC – currently has no registration-supporting studies under way in first-line NSCLC, which combine its PD-1 inhibitor Opdivo with chemotherapy, while Roche is the only company running large-scale Phase III studies.

While Roche's data has gained recognition from analysts and investors since it was published in abstract form ahead of ASCO, this "ground breaking" approach to first-line treatment remains undervalued, argue analysts at Vontobel. The promising data suggest that Roche could assume leadership in the first-line, add analysts, where use of the combination could erode the second-line opportunity as patients become irresponsive after failure in the first-line setting.

With early-stage data indicating that first-line monotherapy use does not confer significant advantages over chemotherapy, but does provide a benefit in terms of tolerability, there could be an opportunity for monotherapy treatment in PD-L1 positive patients (where efficacy is higher) and those patients (approximately 30 percent) intolerant to chemotherapy.

However, if Roche's atezolizumab plus chemotherapy data can be replicated in Phase III studies, this combination could assume significant usage, particularly given the unprecedented uncoupling from a patient's PD-L1 status at baseline, which could support a very broad label, argue analysts.

With PD-1/PD-L1 monotherapy studies in first-line NSCLC targeting PD-L1-positive patients, checkpoint inhibitor combinations (Bristol-Myers Squibb and AstraZeneca are both extensively studying PD-1/PD-L1 inhibitors with a CTLA-4 inhibitor) are aimed largely at PD-L1-negative patients, but are associated with high toxicity (. In a post-ASCO note to investors, analysts at Credit Suisse were left to question whether Roche's atezolizumab plus chemotherapy data has not only significantly raised the efficacy bar, but will prove less costly than a combination of two immunotherapies.

Puchase Reasons

To better ascertain the potential impact of Roche's data in particular, we are asking US and EU5-based oncologists the following questions...

Approximately what one-year progression-free survival benefit would a PD-1/PD-L1 inhibitor + CTLA-4 inhibitor combination have to demonstrate in first-line NSCLC to drive moderate-to-significant uptake?hen generic versions of ADF opioids become available do you think they should be required by the FDA to demonstrate...Additional Details**Publisher** : FirstWord Pharma
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