

Sector comment: Healthcare



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ASCO 2015 – key takeaways

The annual American Society of Clinical Oncology (ASCO) meeting traditionally provides a snapshot of the most exciting clinical programs and science in the field of oncology, a disease category where around 40% of biopharmaceutical research is focused. After three and a half days of clinical/scientific presentations and conversations with key opinion leaders and community oncologists, you get a great sense of where the treatment of cancer is headed.

This year's event in Chicago, not surprisingly, was focused on the area of immuno-oncology, which has already transformed the treatment of melanoma and is in the process of transforming segments of non-small cell lung cancer (NSCLC). Here are some of the key takeaways on this and perhaps a more surprising result with chemotherapy in prostate cancer.

In the CheckMate-017 trial of Opdivo (nivolumab), an anti-PD-1 monoclonal antibody, compared to docetaxel in patients with second-line squamous cell NSCLC, there was a 3.2 month improvement in median overall survival (9.2 vs 6.0, $p=0.00025$). Importantly, this was achieved with a much cleaner toxicology profile with only 7% of patients with Opdivo reporting grade 3-5 adverse events compared to 57% in the docetaxel arm. Surprisingly, response to therapy was not correlated with PD-L1 expression levels.

In CheckMate-067, a trial of Opdivo plus Yervoy (ipilimumab) in advanced melanoma patients, Opdivo plus Yervoy showed a 4.6 month improvement in median progression free survival (PFS) compared to Opdivo alone (11.5 months vs 6.9 months) and a 8.6 month advantage compared to Yervoy (11.5 months vs 2.9 months). However, the toxicity profile deteriorated significantly in the combination arm: grade 3-4 adverse events were 5.1% in the Opdivo arm; 13.2% in the Yervoy arm; and a whopping 55% in the combination arm, while 29.4 % of combination patients had to discontinue treatment due to the severity of the adverse events. Contrary to CheckMate-017, response did correlate with PD-1 levels; clearly more work needs to be done on understanding the predictive value of PD-L1 expression and its relevance to each anti-PD-1 antibody candidate.

While the data are exciting, practicing oncologists believe actual use will be determined by reimbursement issues. Insurers are likely going to be very selective on who they approve to receive therapy, requiring full FDA approval instead of compendia listing in making reimbursement decisions; \$300,000 per patient for combination therapy is simply a very big ticket.

Perhaps one of the most interesting and surprising studies presented at ASCO actually had nothing to do with immuno-oncology and starred chemotherapy. In the STAMPEDE trial which investigated docetaxel plus standard of care (SOC) in hormone-naïve prostate cancer, the docetaxel+SOC combination demonstrated a 10-month survival advantage (77 months vs 67 months, $p=0.003$) vs SOC alone. Importantly, within the M1 subgroup (those with distant metastases) there was a 22-month survival benefit (65 months vs 43 months, $p=0.002$). We suggest these results have the potential to change the treatment paradigm for hormone-naïve prostate cancer patients based on key opinion-leader feedback on the data.

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