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Bristol-Myers' latest PD-1 win could pave the path to earlier use

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Bristol Myers-Squibb ($BMY), a leader among companies at work in immuno-oncology, is pressing for wider use of its lead treatment with new data showing the injected drug could succeed as part of a first-line treatment in lung cancer.

In a Phase Ib study, a combination of Bristol-Myers' immunotherapies Opdivo and Yervoy charted overall response rates as high as 39% when administered to patients with non-small cell lung cancer who hadn't yet received chemotherapy. Median progression-free survival ranged from 4.9 months to 10.6 months across the study's treatment groups, the company said, and combining the two agents demonstrated a similar safety profile to Opdivo alone.

Bristol-Myers tested four dosing regimens of Opdivo, which blocks the protein PD-1, and Yervoy, which targets CTLA-4, laying the groundwork for an ongoing Phase III trial designed to win approval for first-line use in chemo-naive patients. That study, which began in June, is designed to enroll nearly 2,000 patients and determine whether Bristol-Myers' combo can prolong survival better than chemo in NSCLC.

Opdivo, like Merck's ($MRK) rival PD-1 blocker Keytruda, is approved only as a second-line therapy, following Yervoy in melanoma and following chemo in lung cancer. With its new combo efforts, Bristol-Myers is looking to establish the promise of PD-1 inhibition earlier in the treatment process, and success could have a readthrough effect for the whole generation of so-called checkpoint inhibitors, a new class of medications slated to bring in more than $30 billion at its peak, analysts say.

"Overall survival data for Opdivo in the second-line treatment of squamous non-small cell lung cancer marked great progress in immuno-oncology; yet an unmet need remains for first-line treatments that offer durable, long-term survival and greater tolerability," Bristol-Myers Senior Vice President Michael Giordano said in a statement.

Bristol-Myers leads the charge among makers of checkpoint blockers as each works through dozens of clinical trials designed to get its antibody therapy approved in more and more cancer types. Merck secured the first FDA approval for a PD-1 inhibitor last year when Keytruda won agency clearance as a second-line melanoma treatment, but Bristol-Myers quickly caught up with approvals in skin and lung cancers. On their heels are Roche ($RHHBY), whose Phase III atezolizumab has shown particular promise in bladder cancer; and AstraZeneca ($AZN), which is pushing durvalumab through late-stage trials.

The sky-high sales estimates attached to each treatment are dependent on Bristol-Myers and its competitors continuously coming through with promising data in each indication, beginning in the second-line setting and gradually pushing toward standard of care. What remains to be seen is whether payers and providers will shell out for costly immunotherapies as they become more widely indicated. Opdivo and Keytruda hit the market at about $150,000 a year for melanoma, helping push the global oncology market toward $100 billion and spurring debate about the high cost of new cancer agents.

- read the release

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