German Merck, Pfizer immunotherapy shows promise in rare skin cancer

The logo of German pharmaceuticals company Merck is seen at the company's headquarters in Darmstadt, Germany, May 16, 2016.

Reuters/Kai Pfaffenbach

Germany's Merck KGaA (MRCG.DE) on Wednesday reported encouraging interim data against a rare and aggressive form of skin cancer from a mid-stage trial of its experimental drug that helps the immune system attack tumors.

In the 61-patient study, about 30 percent of those with Merkel skin cell carcinoma treated with Merck's avelumab saw their tumors shrink or disappear.

Avelumab, which German Merck is developing with Pfizer Inc (PFE.N), belongs to a class of drugs called PD-L1 inhibitors that block a mechanism tumors use to hide from the immune system, allowing it to recognize and attack the cancer. They are closely related to the PD-1 drugs already on the market from Bristol-Myers Squibb (BMY.N) (Opdivo) and Merck & Co (MRK.N) (Keytruda) seen as major advances against melanoma, lung cancer and other
malignancies.

Roche's (ROG.S) Tecentriq earlier on Wednesday became the first approved PD-L1 drug, gaining U.S. approval to treat advanced bladder cancer.

Patients in the avelumab skin cancer study had not been helped by prior treatment with standard chemotherapy, leaving them without further treatment options, known as second-linetherapy.

"As there are no approved treatments for second-linemetastatic Merkel cell carcinoma and the standard of care isparticipating in clinical trials, these data represent apotential breakthrough for these patients," said LucianoRossetti, head of research for Merck's biopharma business.

The drug was not tested against another medicine or placebo. But researchers concluded from an interim analysis that avelumab demonstrated "a manageable safety profile withdurable responses."

Six patients, or about 10 percent, experienced complete responses with no signs of cancer, while 12 others saw significant tumor shrinkage. The data will be presented at the American Society of Clinical Oncology meeting in Chicago next month, and could be used as a basis for seeking U.S. approval.

The U.S. Food and Drug Administration awarded avelumabits breakthrough designation, which is given to drugs seen as a potentially important advance for specific diseases and can speed up the approval process.

For Merck, which also makes chemicals for display screens and lab supplies, avelumab could help to revive its fortunes in pharmaceuticals after a string of setbacks. For Pfizer, seen as lagging the leaders in the immuno-oncology field, avelumab could be its first significant entry.

The drug is also being tested against lung, breast, gastric and ovarian cancers, and in combination with other medicines.

(Reporting by Ludwig Burger; editing by Bill Berkrot and Nick Zieminski)
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