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Merck, Pfizer brings update on JAVELIN Ovarian 100 Trial of Avelumab

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Merck and Pfizer Inc. announced that data from a planned interim analysis of the Phase III JAVELIN Ovarian 100 study of avelumab did not support the study's initial hypothesis, and therefore the alliance made the decision to terminate the trial in alignment with the independent Data Monitoring Committee.

The Merck-Pfizer alliance was the first to test an immunotherapy in this indication, given the significant unmet need in the treatment of ovarian cancer. Four out of five women with ovarian cancer are diagnosed at advanced stages. Most women with advanced ovarian cancer ultimately die within five years due to refractory, resistant or recurrent disease.

Topline results showed that the study, which is evaluating avelumab in combination with and/or following platinum-based chemotherapy in previously untreated patients with ovarian cancer, would not achieve superiority in the pre-specified primary endpoint of progression-free survival.

While detailed analyses of the data are ongoing, no new safety signals were observed, and the safety profile for avelumab in this trial appears consistent with that observed in the overall JAVELIN clinical development program.

The alliance has notified health authorities and trial investigators of the interim findings and the decision to discontinue the trial. Detailed results will be shared with the scientific community. The JAVELIN Ovarian PARP 100 study and earlier phase studies investigating avelumab in various combinations are ongoing.