

Merck and Pfizer updated Phase III JAVELIN Gastric 300 Study for Advanced Gastric Cancer

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First global trial of a checkpoint inhibitor versus an active chemotherapy comparator rather than placebo in this hard-to-treat patient population



Merck and Pfizer Inc. announced that the Phase III JAVELIN Gastric 300 trial did not meet its primary endpoint of superior overall survival (OS) with single-agent avelumab compared with physician's choice of chemotherapy.

The trial investigated avelumab as a third-line treatment for unresectable adenocarcinoma patients whose disease progressed following two prior therapeutic regimens, regardless of programmed death ligand-1 (PD-L1) expression.

The safety profile of avelumab was consistent with that observed in the overall JAVELIN clinical development program.

"Gastric cancer in the third-line setting is a particularly hard-to-treat and heterogeneous disease, and importantly, this was the first trial conducted with a checkpoint inhibitor compared to an active chemotherapy comparator rather than placebo in a global patient population," said Luciano Rossetti, M.D., E. V. P., Global Head of Research & Development at the Biopharma business of Merck.

"Data from this study will provide valuable information for physicians treating this late stage disease. We remain committed to our ongoing gastric cancer program with avelumab including the JAVELIN Gastric 100 study in the first-line switch maintenance setting." Luciano further commented.

Chris Boshoff (M.D., Sr.V. P. and Head of Immuno-Oncology, Pfizer Global Product Development). said "Gastric cancer is a leading cause of cancer death globally with clear unmet needs, and the results provide important insights as we continue to investigate the role of avelumab for the treatment of gastric cancer,"

Chris continued "With approvals for two cancers in 2017, our companies have made tremendous progress with avelumab on behalf of patients this year, and we are confident that our broad clinical development program in both monotherapy and combinations across a range of cancers will continue to bring new potential treatment options to patients."

The JAVELIN Gastric 300 data will be further examined in an effort to better understand the results and will also be submitted

for presentation at an upcoming medical congress.

The outcome of JAVELIN Gastric 300 does not have any impact on current avelumab approvals.

JAVELIN Gastric 300 is a Phase III, clinical trial investigating avelumab versus physician's choice of protocol-specified chemotherapy plus best supportive care in patients with unresectable adenocarcinoma whose disease has progressed following two prior therapeutic regimens.

The trial enrolled 371 patients from 147 sites in Asia, Australia, Europe, North America and South America. The primary endpoint was OS.

The avelumab gastric clinical development program also includes JAVELIN Gastric 100, a multicenter, randomized, open-label Phase III study.

It evaluates avelumab as first-line maintenance therapy following induction chemotherapy in unresectable gastric cancer. The trial will continue as planned.

Avelumab is under clinical investigation for treatment of gastric/GEJ cancer and has not been demonstrated to be safe and effective for this indication.

There is no guarantee that avelumab will be approved for gastric/GEJ cancer by any health authority worldwide.