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Merck, Pfizer give information of Avelumab in Refractory Ovarian Cancer

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Merck and Pfizer Inc. announced that the Phase III JAVELIN Ovarian 200 trial evaluating avelumab* alone or in combination with pegylated liposomal doxorubicin (PLD), a type of chemotherapy, compared with PLD did not meet the prespecified primary endpoints of overall survival (OS) or progression-free survival (PFS) in patients with platinum-resistant or -refractory ovarian cancer.

"JAVELIN Ovarian 200 enrolled a high proportion of patients with aggressive, refractory disease that had no response to prior platinum-based chemotherapy, a population known to have disease that is challenging to treat; as such, this group of patients is typically not included in Phase III ovarian cancer trials," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-Oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "We initiated the JAVELIN Ovarian 200 trial as the first Phase III study of a checkpoint inhibitor in the platinum-resistant or -refractory setting recognizing these patients has the most pressing need for new treatment options. The results speak to the significant challenges these women face."

"Although OS and PFS did not reach statistical significance, study results indicate potential clinical activity of the combination of avelumab and chemotherapy which will be analyzed further," said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the Biopharma business of Merck. "We thank the patients, their families and the investigators who participated in the JAVELIN Ovarian 200 trial, and wish to underscore that the alliance remains committed to driving advances in ovarian cancer, a commitment that includes two ongoing Phase III trials in previously untreated patients testing avelumab in combination with chemotherapy and, separately, one in combination with chemotherapy followed by maintenance treatment of avelumab in combination with a PARP inhibitor."

Four out of five patients with ovarian cancer are diagnosed at advanced stages. The disease often has no symptoms early on, when it is much more treatable. Approximately 70% of patients with ovarian cancer who receive standard-of-care, frontline, platinum-based chemotherapy will relapse in the first three years. At first relapse, approximately 20% to 25% of ovarian cancer patients have platinum-resistant or -refractory disease, and eventually almost all patients will become platinum-resistant.

JAVELIN Ovarian 200 is a Phase III, multicenter, randomized study investigating the efficacy and safety of avelumab alone or in combination with PLD versus PLD alone in 566 women with ovarian cancer that is resistant or refractory to platinum chemotherapy. The primary objectives were to demonstrate superior OS or PFS for one or both avelumab-based treatment

regimens compared with PLD.

In addition to JAVELIN Ovarian 200, the avelumab ovarian cancer clinical development program includes several ongoing clinical trials investigating avelumab in combination with other therapies. JAVELIN Ovarian 100 is an open-label, international, multicenter, randomized Phase III study of avelumab in combination with and/or as follow-on (maintenance) treatment to platinum-based chemotherapy in previously untreated patients with locally advanced or metastatic (Stage III or Stage IV) epithelial ovarian cancer.

JAVELIN Ovarian 100 is the first Phase III study to evaluate the addition of an immunotherapy to the standard of care in frontline treatment for this aggressive disease. JAVELIN Ovarian PARP 100 is a randomized, open-label, multicenter Phase III study of avelumab plus chemotherapy followed by maintenance therapy of avelumab in combination with a PARP inhibitor or chemotherapy followed by maintenance therapy with a PARP inhibitor, in patients with previously untreated advanced ovarian cancer. Avelumab is also undergoing investigation in combination with other therapies for gynecologic cancers.

*Avelumab is under clinical investigation for treatment of ovarian cancer and has not been demonstrated to be safe and effective for this indication. There is no guarantee that avelumab will be approved for ovarian cancer by any health authority worldwide.