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USFDA accepts GSKâ??s application for ZEJULA (niraparib) in late stage ovarian cancer

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The application was granted priority review and has an action date of 24 October 2019



GlaxoSmithKline has announced that TESARO, an oncology-focused business acquired by GSK, submitted a supplemental New Drug Application (sNDA) to the USFDA for ZEJULA (niraparib).

The application was granted priority review and has an action date of 24 October 2019.

The sNDA supports a potential new indication for the treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer patients who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with either BRCA mutation or Homologous recombination deficiency (HRD) and have progressed more than six months after the last platinum-based chemotherapy.

Mary Lynne Hedley, President and Chief Operating Officer of TESARO, said, “The results of the QUADRA study demonstrate that ZEJULA is active as a late-line treatment for patients beyond those with BRCA mutations. With this study, we continue to advance our mission to provide more patients with ovarian cancer an opportunity to benefit from treatment with ZEJULA.”

Dr Hal Barron, Chief Scientific Officer and President, R&D, GSK, said: “We know ZEJULA plays an important role in helping women with ovarian cancer whose disease has progressed despite initial therapy. Our hope is that over time, our ongoing clinical trials will demonstrate that this medicine can benefit even more patients.”

The niraparib sNDA is supported by data from the QUADRA trial. Data from the QUADRA trial were recently published in Lancet Oncology.

QUADRA is a large multicenter, open-label, single-arm, phase 2 study that evaluated the safety and activity of niraparib in adult patients with relapsed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who were treated with three or more previous chemotherapy regimens. Patients received oral niraparib 300 mg once daily continuously until disease progression.

The primary objective was the proportion of patients achieving an investigator-assessed confirmed overall response in patients with homologous recombination deficiency (HRD)-positive tumours (including patients with BRCA and without BRCA mutations) sensitive to their last platinum-based therapy. Additional objectives of the study was to evaluate the efficacy of niraparib in the broad late-line ovarian cancer population overall, and in subgroups defined by clinical and molecular biomarkers, such as platinum-sensitivity and BRCAmut and HRD status.”

Approximately 22,000 women are diagnosed each year with ovarian cancer in the United States, and more than 65,000 women are diagnosed annually in Europe. Ovarian cancer is the fifth most frequent cause of cancer death among women. Despite high response rates to platinum-based chemotherapy in the second-line advanced treatment setting, approximately 85% of patients will experience recurrence within two years.

TESARO, an oncology-focused business within GSK, devoted to providing transformative therapies to people facing cancer.