News

Merck's trial of Keytruda regimen fails to meet primary endpoint

The randomised, double-blind study involved 1,095 patients to assess adjuvant treatment with Keytruda plus chemotherapy.

May 10, 2024

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The safety profile of MSD's Keytruda was in line with those in prior studies. Credit: Atmosphere1 / Shutterstock.com.

Merck & Co (MSD) has announced that its Phase III KEYNOTE-B21 (ENGOT-en11/GOG-3053) clinical trial of Keytruda plus chemotherapy in patients with newly diagnosed high-risk endometrial cancer following surgery with curative intent, failed to meet its primary endpoint.

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IPR2024-00649

Sponsored by MSD, the trial is being carried out in collaboration with the European Network for Gynecologic Oncology Trial (ENGOT) groups and the GOG Foundation.

The randomised, double-blind study involved 1,095 patients to assess adjuvant treatment with Keytruda plus chemotherapy, irrespective of radiotherapy status versus adjuvant placebo plus chemotherapy, with or without radiotherapy.

The primary endpoints are disease-free survival (DFS) and overall survival (OS), and secondary endpoints include safety.

According to the data from an interim analysis by an independent data monitoring committee, the Keytruda regimen failed to show DFS improvement versus placebo.

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The secondary goal of OS was not tested due to the lack of superiority in DFS.

Keytruda's safety profile was in line with those in prior studies without any new safety signals detected.

The comprehensive data analysis from the trial is currently underway.

Keytruda has existing approvals in the US for certain types of advanced endometrial carcinoma.

It is approved in combination with Lenvima for mismatch repair proficient (pMMR) advanced endometrial carcinoma patients after disease progression post-systemic therapy.

It is also approved as a monotherapy for MSI-H or mismatch repair deficient advanced endometrial carcinoma patients who have advanced post-systemic therapy and are not eligible for curative surgery or radiation.

Merck Research Laboratories global clinical development vice-president Dr Gursel Aktan said: "While these results were not what we had hoped, we are focused on continuing to build on the established role of Keytruda in advanced endometrial carcinoma through our approved indications, while rapidly progressing clinical research evaluating Keytruda-based combinations and other investigational candidates, including antibody-drug conjugates, in endometrial and other types of gynecologic malignancies."

Earlier this month, MSD reported the final analysis findings from the Phase III KEYNOTE-811 trial of Keytruda plus trastuzumab and chemotherapy to treat human epidermal growth factor receptor 2 (HER2)-positive locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma.

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