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GSK announces FIRST trial met its primary endpoint of progression free survival in first line advanced ovarian cancer

- Addition of *Jemperli* (dostarlimab) to both platinum-based chemotherapy and *Zejula* (niraparib) maintenance, with or without bevacizumab, demonstrated a statistically significant effect on progression free survival (PFS) versus active comparator arm

GSK plc (LSE/NYSE: GSK) today announced headline results from the FIRST-ENGOT-OV44 phase III trial evaluating *Zejula* (niraparib) and *Jemperli* (dostarlimab) in first line advanced ovarian cancer. The trial met its primary endpoint of PFS demonstrating a statistically significant difference with the addition of dostarlimab to both standard of care carboplatin-paclitaxel chemotherapy and niraparib maintenance, with or without bevacizumab.

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: “As part of our focus in gynaecological cancers, we continue to evaluate the potential of this combination and look forward to sharing full results from the trial.”

The key secondary endpoint of overall survival (OS) did not meet statistical significance. Further analyses are ongoing and data will be shared with health authorities and presented at an upcoming scientific meeting.

The safety and tolerability profile was generally consistent with the known safety profiles of the individual agents.

About ovarian cancer

Ovarian cancer is the eighth most common cancer in women worldwide.¹ Despite high response rates to platinum-based chemotherapy in the first-line setting, approximately 85% of patients will experience disease recurrence. Once the disease recurs, it is rarely curable, with decreasing time intervals to each subsequent recurrence.²

About the FIRST trial

The FIRST-ENGOT-OV44 trial is an international, double-blind, randomised phase III ENGOT trial sponsored by GSK and led by GINECO, a French cooperative group dedicated to gynecological oncology. FIRST is investigating the addition of dostarlimab to both, standard of care (SOC) platinum-based chemotherapy and niraparib maintenance, with or without bevacizumab, as a first-line treatment of stage III or IV nonmucinous epithelial ovarian cancer. Originally, participants were randomised 1:1:2 into three groups: Arm 1: SOC chemotherapy followed by placebo maintenance; Arm 2: SOC chemotherapy followed by niraparib maintenance; Arm 3: SOC chemotherapy and dostarlimab followed by niraparib and dostarlimab maintenance. Bevacizumab could be added at the investigator's discretion across all arms. Due to the approvals of PARP inhibitors in the first-line setting, Arm 1 (n=193) was closed and participants were subsequently randomized 1:2 to Arms 2 (n= 385) and 3 (n= 753) only. The primary endpoint is investigator-assessed PFS in Arms 2 and 3. Secondary endpoints include OS, PFS2, time to first and second subsequent therapy.

ABOUT GINECO³

GINECO (Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein) is the French Cooperative Group in Oncology labelled by INCa (Institut National du Cancer or French NCI) developing and conducting gynecological and metastatic breast cancer clinical trials at the national and international level. The GINECO group was founded in 1993 and is member of international consortia such as ENGOT and GCIG (Gynecologic Cancer InterGroup).

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About ENGOT⁴

The European Network for Gynaecological Oncological Trial (ENGOT) groups is a research network of the European Society of Gynaecological Oncology and was founded in Berlin in October 2007. Currently, ENGOT consists of 21 trial groups from 31 European countries that perform cooperative clinical trials. ENGOT's ultimate goal is to bring the best treatment to gynaecological cancer patients through the best science and enabling every patient in every European country to access a clinical trial.

About *Jemperli* (dostarlimab)

Jemperli, a programmed death receptor-1 (PD-1)-blocking antibody, is the backbone of GSK's ongoing immunology-based research and development programme. A robust clinical trial programme includes studies of *Jemperli* alone and in combination with other therapies for gynaecologic, colorectal and lung cancers, as well as where there are opportunities for transformational outcomes.

In the US, *Jemperli* is indicated in combination with carboplatin and paclitaxel, followed by *Jemperli* as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer. This includes patients with mismatch repair proficient/microsatellite stable (MMRp/MSS) and dMMR/MSI-H tumours. *Jemperli* is also approved as a single agent for adult patients with dMMR recurrent or advanced endometrial cancer, as determined by a US FDA-approved test, that has progressed on or following a prior platinum-containing regimen in any setting and are not candidates for curative surgery or radiation. Additionally, *Jemperli* is indicated in the US for patients with dMMR recurrent or advanced solid tumours, as determined by a US FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. The latter indication is approved in the US under accelerated approval based on tumour response rate and durability of response. Continued approval for this indication in solid tumours may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Jemperli was discovered by AnaptysBio, Inc. and licensed to TESARO, Inc., under a collaboration and exclusive license agreement signed in March 2014. Under this agreement, GSK is responsible for the ongoing research, development, commercialisation, and manufacturing of *Jemperli*, and cobolimab (GSK4069889), a TIM-3 antagonist.

Important Information for *Jemperli* in the EU

Indications

Jemperli is indicated:

- in combination with carboplatin-paclitaxel, for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy;
- as monotherapy for treating adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.

Refer to the *Jemperli* EMA Reference information (www.ema.europa.eu/en/medicines/human/EPAR/jemperli) for a full list of adverse events and the complete important safety information in the EU.

About *Zejula* (niraparib)

Zejula is an oral, once-daily Poly (ADP-ribose) polymerase (PARP) inhibitor indicated in the US for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy; and for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian

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tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy and who have been selected based on a US FDA-approved companion diagnostic for *Zejula*.

Important Information for *Zejula* in the EU

Indications

Zejula is indicated:

- as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.
- as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Refer to the *Zejula* EMA Reference Information

(<https://www.ema.europa.eu/en/medicines/human/EPAR/zejula>) for a full list of adverse events and the complete important safety information in the EU.

GSK in oncology

Oncology is an emerging therapeutic area for GSK where we are committed to maximising patient survival with a current focus on haematologic malignancies, gynaecologic cancers, and other solid tumours through breakthroughs in immuno-oncology and tumour-cell targeting therapies.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com](https://www.gsk.com).

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

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 3. Association for Research on Cancers including GINECO. Available at: <https://www.arcagy.org/>. Accessed 20 November 2024.
 4. European Network of Gynaecological Oncological Trial groups. Available at: <https://engot.esgo.org/>. Accessed 20 November 2024.