GSK to highlight the latest advances in cancer research from across its portfolio and pipeline at ESMO

GSK PUBLISHED SEP 1, 2022 BY <u>GSK</u>

For media and investors only

Long-term data presented adds further evidence to the role of Zejula in the first-line maintenance setting for advanced ovarian cancer

Additional data for Jemperli demonstrates its potential in patients with mismatch repair-deficient (dMMR) recurrent or advanced solid tumours, including endometrial cancer

GSK plc (LSE/NYSE: GSK) will present new findings from across its diverse oncology portfolio and pipeline at the European Society for Medical Oncology (ESMO) Congress 2022 (9-13 September), including presentations on Zejula (niraparib) and Jemperli (dostarlimab), as well as early-stage research in immuno-oncology and real-world evidence assessing treatment patterns and outcomes. The research being presented will further demonstrate the potential of GSK's approved therapies and commitment to exploring new approaches that target key pathways and maximise anti-tumour activity.

Hesham Abdullah, SVP, Global Head of Oncology Development, GSK said:

The long-term data we are presenting at ESMO further our understanding of the role of Zejula and Jemperli to treat certain ovarian and endometrial cancers, highlighting our commitment to gynaecological cancers, and will provide the oncology community with deeper insights to inform treatment decisions and help optimise outcomes for patients. We look forward to presenting research that continues to explore the full potential of our approved and investigational therapies, as we seek to improve outcomes for more patients.

Transforming the lives of patients with gynaecologic malignancies

A long-term, ad-hoc analysis from the phase III PRIMA (ENGOT-OV26/GOG-3012) study evaluating niraparib as a maintenance monotherapy in patients with first-line ovarian cancer following a response to platinum-based chemotherapy (presentation #530P) will reinforce the role of this poly (ADP-ribose) polymerase (PARP) inhibitor for this difficult-to-treat cancer.

Long-term data in mismatch repair-deficient solid tumours

Updated results from the GARNET trial will further demonstrate the potential of dostarlimab, a programmed cell death receptor-1 (PD-1) blocking antibody, in the treatment of advanced solid tumours. This includes a longer-term analysis from cohorts A1 and F of the study, evaluating overall survival (OS) and progression-free survival (PFS) in certain patients with mismatch repair-deficient (dMMR) recurrent or advanced solid tumours (presentation #549P), showcasing our commitment across tumour types.

Understanding real-world outcomes to advance patient care

GSK will also present a real-world analysis of patients with dMMR/microsatellite instability-high (MSI-H) endometrial cancer who received early access to dostarlimab via the temporary authorisation for use (ATU) programme in France, highlighting the need for patient access to new treatment regimens (presentation #553P).

Findings also will be presented from primary and secondary research demonstrating the variation in perspectives of regulators, payors, oncologists, and patients on non-OS or surrogate endpoints, and potential strategies to bridge gaps in value attribution (presentation #1317MO).

Full list of GSK's presentations at ESMO:

| Abstract Name | Presenter | Presentation Details |

| PRIMA/ENGOT-OV26/GOG-3012 study: updated long-term PFS and safety | A. González-Martín | #530P |

| Phase 1b study of elimusertib (ATRi; BAY 1895344) in combination

with niraparib (PARPi) in patients with advanced solid tumors | T. Yap | #494TiP |

| Abstract Name | Presenter | Presentation Details |

| Efficacy of dostarlimab in endometrial cancer (EC) by molecular subtype: a post hoc analysis of the GARNET study| A. Oaknin | #547P |

| Progression-free survival (PFS) and overall survival (OS) in advanced/recurrent (AR) mismatch repair deficient/microsatellite instability-high or proficient/stable (dMMR/MSI-H or MMRp/MSS) endometrial cancer (EC) treated with dostarlimab in the GARNET study| A. Tinker | #548P |

| Progression-free survival (PFS) and overall survival (OS) in patients (pts) with mismatch repair deficient (dMMR) solid tumors treated with dostarlimab in the GARNET study| T. Andre | #549P |

| Real-world data on dostarlimab in post-platinum mismatch repair deficient (dMMR)/ microsatellite instability high (MSI-H) advanced/recurrent (A/R) endometrial cancer: descriptive analysis of the French cohort Temporary Authorization of Use (ATU)| M. Rodrigues | #553P |

| Abstract Name | Presenter | Presentation Details |

| METEOR-1: A phase 1 study of the safety and efficacy of the protein arginine methyltransferase 5 (PRMT5) inhibitor GSK3326595 in advanced solid tumors| S. Postel-Vinay | #456MO |

| Phase 2 study of anti-TIGIT GSK4428859A (GSK'859A)/EOS-448 + anti-CD96 GSK6097608 (GSK'608) + anti-PD-1 dostarlimab in nonsmall cell lung cancer (NSCLC)| D. Spigel | #1189TiP |

| Abstract Name | Presenter | Presentation Details |

| Non-OS endpoints in oncology: strategies to bridge the gap in value attribution by regulators, payors, oncologists, and patients| A. Fameli | #1317MO |

| Frequency and impact of retreatment in relapsed refractory multiple myeloma (RRMM): Real-world survey conducted in 5 European countries (United Kingdom, France, Germany, Italy, Spain) | A. Bailey | #642P |

| Treatment patterns, outcomes, and physician decision-making in multiple myeloma: a real-world European study| A. Ribbands | #644P |

Full list of investigator-sponsored studies and supported collaborative studies at ESMO:

| Abstract Name | Presenter | Presentation Details |

| NIRVANA-1: A multicentre randomized study comparing carboplatinpaclitaxel (CP) followed by niraparib (nira) to CP-bevacizumab (bev) followed by nira-bev in patients with FIGO Stage III ovarian high-grade epithelial cancer and no residual disease after upfront surgery | G. Freyer | #615TiP |

| Abstract Name | Presenter | Presentation Details |

| Prevalence and clinical characteristics of metastatic synovial sarcoma (mSS) patients with tumours expressing NY-ESO-1 antigen (NY+) and who are HLA-A*02:01, *02:05 or *02:06 allele positive (HLA+): Cohort study from the French Sarcoma Group| A. Dufresne | #1503P |

Ovarian cancer is the 8th most common cancer in women worldwide.Despite high response rates to platinum-based chemotherapy in the front-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.

Endometrial cancer is found in the inner lining of the uterus, known as the endometrium. It is the most common gynaecologic cancer in the US and second most common gynaecologic cancer globally. Approximately 15-20% of women with endometrial cancer will be diagnosed with advanced disease at the time of diagnosis.

Multiple myeloma is the third most common form of blood cancer in the US. An estimated 35,000 Americans are diagnosed with the disease annually and nearly half (13,000 people) will die from it. Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments. Dostarlimab is a programmed death receptor-1 (PD-1)-blocking antibody that binds to the PD-1 receptor and blocks its interaction with the PD-1 ligands PD-L1 and PD-L2.In addition to GARNET, dostarlimab is being investigated in other registrational enabling studies, as monotherapy and as part of combination regimens, including in women with recurrent or primary advanced endometrial cancer, women with stage III or IV non-mucinous epithelial ovarian cancer, and in patients with other advanced solid tumours or metastatic cancers.

Dostarlimab was discovered by AnaptysBio and licensed to TESARO, Inc., under a Collaboration and Exclusive License Agreement signed in March 2014. The collaboration has resulted in three monospecific antibody therapies that have progressed into the clinic. These are: dostarlimab (GSK4057190), a PD-1 antagonist; cobolimab (GSK4069889), a TIM-3 antagonist; and GSK4074386, a LAG-3 antagonist. GSK is responsible for the ongoing research, development, commercialisation, and manufacturing of each of these assets under the Agreement.

Important Information for JEMPERLI in the EU

JEMPERLI is indicated as monotherapy for the treatment of 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 Prescribing Information for a full list of adverse events and the complete important safety information in the EU.

Niraparib is an oral, once-daily PARP inhibitor that is currently being evaluated in multiple pivotal trials. GSK is building a robust niraparib clinical development programme by assessing activity across multiple tumour types and by evaluating several potential combinations of niraparib with other therapeutics. The ongoing development programme for niraparib includes several combination studies.

Important Information for ZEJULA in the EU

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.

Refer to the ZEJULA Prescribing Information for a full list of adverse events and the complete important safety information in the EU.

GSK is focused on maximising patient survival through transformational medicines. GSK's pipeline is focused on immunooncology, cell therapy, tumour cell targeting therapies and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilising modalities such as small molecules, antibodies, antibody-drug conjugates and cell therapy, either alone or in combination.

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 <u>gsk.com/company</u>

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 in the Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

Worldwide Cancer Data. World Cancer Research Fund. https://www.wcrf.org/dietandcancer/cancer-trends/worldwide-can.... Updated January 10, 2022. Accessed January 2022.

Lorusso D, Mancini M, Di Rocco R, et al. The role of secondary surgery in recurrent ovarian cancer [published online August 5, 2012]. Int J Surg Oncol. 2012. doi:10.1155/2012/613980.

Braun MM, et al. Am Fam Physician. 2016;93(6):468-474.

Kantar Health, Cust Study (2018).

Islamni F, Ward E, Sung H et al. Annual Report to the Nation on the Status of Cancer– National Cancer Institute.

https://seer.cancer.gov/report_to_nation. Published July 2021. Accessed February 2022.

Key Statistics About Multiple Myeloma. American Cancer Society. Available at: <u>https://www.cancer.org/cancer/multiple-</u> <u>myeloma/about/key-stati...</u>. Accessed February 2022.

Nooka AK, Kastritis E, Dimopoulos MA. Treatment options for relapsed and refractory multiple myeloma. Blood. 2015;125(20)

Laken H, Kehry M, Mcneeley P, et al. Identification and characterization of TSR-042, a novel anti-human PD-1 therapeutic antibody. European Journal of Cancer. 2016;69,S102. doi:10.1016/s0959-8049(16)32902-1.

Press release distributed by Wire Association on behalf of GSK, on Sep 1, 2022. For more information subscribe and <u>follow</u> us.

Media Assets

Embedded Media

Visit the <u>online press release</u> to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-to-highlightthe-latest-advances-in-cancer-research-from-across-its-portfolio-andpipeline-at-esmo-1824

GSK

Newsroom: <u>https://wireassociation.eu/newsroom/gsk</u> Website: https://www.gsk.com/ Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK Twitter - http://twitter.com/GSK Youtube - http://www.youtube.com/GSK Linkedin - http://www.linkedin.com/company/glaxosmithkline Instagram - https://www.instagram.com/gsk/