GSK to highlight continued progress in oncology pipeline and portfolio with data presented at ESMO

PUBLISHED SEP 9, 2021
BY GSK

For media and investors only

Issued: 9 September 2021, London UK

Data demonstrate potential of oncology pipeline and reinforce the importance of JEMPERLI (dostarlimab) and ZEJULA (niraparib) as treatment options

GlaxoSmithKline (GSK) plc will present new data across the Company's oncology pipeline and portfolio at the upcoming European Society for Medical Oncology (ESMO) Congress 2021 (16-21 September), including new data on JEMPERLI (dostarlimab) and ZEJULA (niraparib), as well as early-stage research in immuno-oncology and oncology cell therapy. With 13 presentations at the meeting (12 GSK-sponsored and one GSK-supported), GSK will demonstrate its momentum in advancing dostarlimab and niraparib, and provide new insights into investigational therapies through early-stage research.

The data being presented at ESMO reflect GSK's commitment to strengthening its oncology pipeline across its focus areas of immuno-oncology, synthetic lethality and oncology cell therapy. GSK has a diverse portfolio and pipeline, including three marketed oncology medicines and 16 assets in clinical development that leverage the science of the immune system, human genetics and advanced technologies to address a variety of tumour types.

Continuing to advance immuno-oncology therapies

Presentations from the phase I GARNET study will address anti-tumour activity by tumour mutational burden in patients with recurrent

or advanced endometrial cancer (Abstract #76P) in addition to treatment-related adverse events occurring during the study (Abstract #991P). GSK will also present a real-world analysis of the demographics and survival outcomes in patients from England with advanced or recurrent endometrial cancer following platinum-based doublet therapies (Abstract #812P).

Dostarlimab is the first anti-PD-1 monotherapy approved for endometrial cancer in the European Union (EU) and received a conditional approval in April for the treatment of women with mismatch repair-deficient (dMMR) /microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer who have progressed on or following prior treatment with a platinum containing regimen. The treatment also received accelerated approval in the United States (US) for adult patients with dMMR recurrent or advanced endometrial cancer, as determined by an FDA-approved test, who have progressed on or following prior treatment with a platinum-containing regimen.

Last month, the FDA granted accelerated approval of an additional indication for dostarlimab for the treatment of adult patients with dMMR recurrent or advanced solid tumours, as determined by an FDA-approved test, who have progressed on or following prior treatment and who have no satisfactory alternative treatment options. The new indication for dostarlimab is the fourth approval for GSK oncology in less than 1.5 years, demonstrating GSK's unyielding commitment to address the unmet needs of cancer patients.

Continued research and development in synthetic lethality

Results from the phase III PRIMA trial will examine quality-adjusted time without symptom or toxicity of niraparib in patients with advanced ovarian cancer (Abstract #738P). Additionally, GSK will present real-world analyses from three studies in patients with advanced ovarian cancer across the UK, France and US.

Niraparib is a once-daily oral monotherapy maintenance treatment approved for women with first-line platinum-responsive advanced ovarian cancer regardless of biomarker status in the US and the EU. The research that will be presented at ESMO bolsters the understanding of the use of this poly (ADP-ribose) polymerase (PARP) inhibitor for maintenance treatment in ovarian cancer.

GSK will also present a trial in progress poster on the recently

initiated phase III ZEAL-1L study in advanced or metastatic non-small cell lung cancer, expanding the Company's clinical development programme into other solid tumours to potentially bring niraparib to more patients.

The complete list of GSK sponsored and supported abstracts accepted by ESMO for presentation and/or publication from the company's areas of oncology research is below.

| Abstract Name | Presenter | Abstract Number |

| Analysis of antitumor activity of dostarlimab by tumor mutational burden (TMB) in patients (pts) with endometrial cancer (EC) in the GARNET trial| Oaknin, A | #76P |

| Demographics and survival outcomes in patients with advanced or recurrent endometrial cancer (EC) following platinum-based doublet (PBD) in the English real-world (RW) setting| Heffernan, K | #812P |

| Treatment-related adverse events (TRAEs) occurring during dostarlimab therapy in the GARNET study | Andre, T | #991P |

| ENGOT-EN6/GOG-3031/NSGO-RUBY Part 2: A phase 3, randomized, double-blind, study of dostarlimab + carboplatin-paclitaxel followed by

dostarlimab + niraparib versus placebo (PBO) + carboplatin-paclitaxel followed by PBO in recurrent or advanced endometrial cancer (EC) | Mirza, MR | #820TiP |

| Adverse event management during treatment with bintrafusp alfa, a bifunctional fusion protein targeting TGF-β and PD-L1: treatment guidelines based on experience in clinical trials| Gulley, J | #1689P |

| Long-term follow-up of patients (pts) with human papillomavirus (HPV)–associated malignancies treated with bintrafusp alfa, a bifunctional fusion protein targeting TGF-β and PD-L1| Strauss, J | #957O |

| Abstract Name | Presenter | Presentation Details |

| Impact of residual disease on outcomes in patients with ovarian cancer: A meta-analysis | Chase, D | #761P |

| Ovarian Cancer Retrospective European (O'CaRE) observational study to assess burden of disease and time to next treatment in real-world clinical practice: results from the United Kingdom (UK)| McGrane, J | #745P |

| Quality-Adjusted Time without Symptom or Toxicity (Q-TWiST) and Quality-Adjusted Progression-Free Survival (QA-PFS) of First-Line (1L) maintenance niraparib in patients with advanced Ovarian Cancer (OC) – Results from the PRIMA trial| Barretina-Ginesta, P | #738P |

| Real-world clinical outcomes of patients with de novo advanced high-grade epithelial ovarian cancer eligible to niraparib maintenance in France| Rodrigues, M | #746P |

| Survival in patients (pts) with advanced ovarian cancer (AOC) changes with cumulative number of risk factors (RFs), a US real-world (RW) analysis| Chase, D | #742P |

| First-line (1L) maintenance therapy with niraparib (nira) + pembrolizumab (pembro) vs placebo + pembro in advanced/metastatic non-small cell lung cancer (NSCLC): Phase III ZEAL-1L study| Ramalingam, S | #1360TiP |

| Abstract Name | Presenter | Presentation Details |

| A novel, comprehensive glimpse at NY-ESO-1 expression, mRNA to protein translation, & potential impact on clinical studies| Blouch, K | #109P |

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, 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 Products 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

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.

GSK is focused on maximising patient survival through transformational medicines. GSK’s pipeline is focused on immuno-oncology, 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 science-led global healthcare company. For further information please visit www.gsk.com/about-us.

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 2020 and any impacts of the COVID-19 pandemic.

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 9, 2021. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-to-highlight-continued-progress-in-oncology-pipeline-and-portfolio-with-data-presented-at-esmo-1915

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
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/