GSK to showcase scientific advances and progress in oncology at ASCO and EHA

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Company will share findings from 34 abstracts at oncology annual scientific congresses American Society of Clinical Oncology and European Hematology Association spanning priority areas of cancer research, including immuno-oncology, synthetic lethality and cell therapy.

For media and investors only

GlaxoSmithKline (GSK) plc will present new data from key focus areas within its oncology portfolio at the upcoming 2021 American Society of Clinical Oncology (ASCO) Annual Meeting (4-8 June) and the European Hematology Association (EHA) 2021 Virtual Congress (9-17 June).

GSK will showcase innovative approaches to oncology R&D and cutting-edge science at the upcoming ASCO and EHA meetings. The company will present new data on its approved therapies, BLENREP (belantamab mafodotin), JEMPERLI (dostarlimab) and ZEJULA (niraparib), as well as its investigational T cell receptor T-cell therapy (TCR-T) letetresgene autoleucel (lete-cel; GSK3377794) for solid tumours.

Dr Axel Hoos, Senior Vice President and Head of Oncology R&D, GSK said:

The data we will share at ASCO and EHA demonstrate the continued strengthening of our oncology R&D pipeline in our focus areas of immuno-oncology, cell therapy and synthetic lethality. We are committed to ensuring our three approved medicines – niraparib, belantamab mafodotin and dostarlimab – help as many patients as possible while exploring novel approaches to expand treatment options for the millions of lives impacted by cancer each year.

Continuing GSK's momentum in immuno-oncology

Dostarlimab, a programmed death receptor-1 (PD-1) blocking antibody, received accelerated approval in the US in April 2021 for certain women with mismatch repair-deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test who have progressed on or following prior treatment with a platinumcontaining regimen. In addition, in April dostarlimab also received a conditional approval in the EU for the treatment of women with dMMR/microsatellite instability-high (MSI-H) endometrial cancer. Data from the registrational GARNET trial of dostarlimab in multiple tumour types will be presented at ASCO, including an interim combined efficacy and safety analysis of the endometrial and pan-tumour cohorts (ASCO abstract #2564).

Additionally, GSK will present new data regarding the management of adverse events associated with belantamab mafodotin in relapsed/refractory multiple myeloma (ASCO abstract #8033; EHA abstracts #EP1026 and #PB1698). Belantamab mafodotin is an anti-BCMA (B-cell maturation antigen) treatment that received accelerated and conditional approvals in the US and EU, respectively, for adult patients with relapsed/refractory multiple myeloma who have received at least four prior therapies, including an anti-CD38 antibody, a proteasome inhibitor and an immunomodulatory agent.

Updates from GSK's efforts in synthetic lethality

GSK will share data from combined analysis of three phase III studies in patients with BRCA mutated ovarian cancer, examining the efficacy of niraparib, as well as its safety profile (ASCO abstract #5518). This research adds to the understanding of the use of this poly (ADPribose) polymerase (PARP) inhibitor for maintenance treatment in ovarian cancer. GSK remains committed to fully exploring the potential of niraparib, with clinical trials underway evaluating it in ovarian cancer in combination with other therapies and in other solid tumours.

GSK's latest research in oncology cell therapy

Lete-cel, GSK's leading cell therapy asset, is a potential first-in-class TCR-T consisting of modified T cells designed to recognise the NY-ESO-1 antigen, which is present across multiple solid tumours, including synovial sarcoma and myxoid/round cell liposarcoma. A presentation of note will include findings from an interim analysis on the safety and efficacy of lete-cel in myxoid/round cell liposarcoma (ASCO abstract #11521). With three programmes currently in clinical development and an emerging pipeline of enhancement technologies and targets, cell therapy in solid tumours is a key pillar of GSK's broader oncology strategy to help address unmet patient needs.

The complete list of GSK sponsored abstracts accepted by ASCO and EHA for presentation/ publication from the company's areas of cancer research is below.

| Abstract Name | Presenter | Abstract Number |

Antitumor activity of dostarlimab in patients with mismatch mutation repair-deficient/microsatellite instability-high tumours: A combined analysis of 2 cohorts in the GARNET study| Berton, D. | #2564 |

| Inducible T-cell co-stimulatory (ICOS) receptor agonist, feladilimab (fela), alone and in combination (combo) with pembrolizumab (P): Results from INDUCE-1 urothelial carcinoma (UC) expansion cohorts (ECs)| Balar, A. | #4519 |

 \mid Evaluation of bintrafusp alfa, a bifunctional fusion protein targeting TGF- β and PD-L1, in cervical cancer: Data from phase 1 and phase 2 studies \mid Strauss, J. \mid #5509 \mid

| Long-term follow-up of bintrafusp alfa, a bifunctional fusion protein targeting TGF- β and PD-L1, in advanced squamous cell carcinoma of the head and neck (SCCHN)| Chul Cho, B. | #6020 |

| Relationship between corneal exam findings, best-corrected visual acuity (BCVA), and ocular symptoms in patients with relapsed or refractory multiple myeloma (RRMM) receiving belantamab mafodotin (belamaf)| Terpos, E. | #8033 |

| Evolution of standard of care therapies used for recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC): A real-world analysis of patient health records from 2016 to 2019| Saba, N.F. | #e18728 |

| Landscape review of the patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE) in oncology: Adoption and recent learnings| Regnault, A. | # e18587 | | Real-world treatment patterns and outcomes of triple-exposed multiple myeloma patients treated in community oncology practices in the United States| Smith, R. | #e18727 |

| Treatment patterns among patients with advanced/recurrent endometrial

cancer in the United States | Maiese, E.M. | #e18693 |

| Abstract Name | Presenter | Presentation Details |

| Niraparib efficacy and safety in patients with BRCA mutated (BRCAm) ovarian cancer: Results from three phase 3 niraparib trials| Gonzalez-Martin, A. | #5518 |

| Real-world patterns and predictors of first-line maintenance use among newly diagnosed advanced ovarian cancer: Is there an opportunity for change?| Liu, J. | #e18710 |

| Real-world progression free survival among newly diagnosed advanced ovarian cancer: Does maintenance therapy work?| Liu, J. | #e18707 |

| Tissue distribution and brain penetration of niraparib in tumour bearing mouse models and its clinical relevance| Gada, K. | #e15066 |

| Abstract Name | Presenter | Presentation Details |

| IGNYTE-ESO: A master protocol to assess safety and activity of letetresgene autoleucel (lete-cel; GSK3377794) in HLA-A*02+ patients with synovial sarcoma or myxoid/round cell liposarcoma (Substudies 1 and 2)| D'Angelo, S. | #TPS11582 |

| Master protocol to assess safety and recommended phase 2 dose of next generation NY-ESO-1-specific TCR T-cells in HLA-A*02 patients with synovial sarcoma or non-small cell lung cancer (Substudies 1 and 2)| Schoenfeld, A. | #TPS2661 |

| Safety and efficacy of letetresgene autoleucel (lete-cel; GSK3377794) in advanced myxoid/round cell liposarcoma (MRCLS) following high lymphodepletion (Cohort 2): Interim analysis| D'Angelo, S. | #11521 |

| Abstract Name | Presenter | Presentation Details |

| Real-world treatment patterns among advanced HR+/HER2- breast cancer patients in the post-CDK4/6 inhibitor era: An analysis of administrative claims data| Boyle, T. A. | #e18695 |

| Abstract Name | Presenter | Presentation Details |

| Characterization of ocular adverse events in patients receiving belantamab mafadotin for ≥12 months: post-hoc analysis of DREAMM-2 study in relapsed/refractory multiple myeloma| Lonial, S. | #EP1026

| Relationship between corneal exam findings, best-corrected visual acuity (BCVA), and ocular symptoms in patients with relapsed or refractory multiple myeloma (RRMM) receiving belantamab mafodotin (belamaf)| Terpos, E. | #EP1001 |

| DREAMM-5 platform trial: Belantamab mafodotin (belamaf) in combination with five different novel agents in patients with relapsed/refractory multiple myeloma (RRMM)| Richardson, P. | #PB1698 |

| Landscape review of the patient-reported outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) in Oncology: Adoption and recent learnings| Regnault, A. | #EP1171 |

About Belantamab Mafodotin

Belantamab mafodotin is an antibody drug conjugate comprising a humanised anti-B cell maturation antigen (BCMA) monoclonal antibody conjugated to the cytotoxic agent auristatin F via noncleavable linker. The drug linker technology is licensed from Seagen; monoclonal antibody is produced using POTELLIGENT Technology licensed from BioWa.

Important information for BLENREP in the EU

BLENREP is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. Refer to the BLENREP Prescribing Information for a full list of adverse events and the complete important safety information.

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 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) highgrade 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 immunooncology, cell therapy, cancer epigenetics 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 with a special purpose: to help people do more, feel better, live longer. For further information please visit <u>www.gsk.com/about-us</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 2020 and any impacts of the COVID-19 pandemic.

Thomas R, Al-Khadairi G, Roelands J, et al.

NY-ESO-1 Based Immunotherapy of Cancer: Current Perspectives.

Frontiers in Immunology, Frontiers Media S.A., 1 May 2018, <u>www.ncbi.nlm.nih.gov/pmc/articles/PMC5941317/</u>.

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 Jun 1, 2021. For more information subscribe and <u>follow</u> us.

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