GSK unveils latest research advances demonstrating strength of its portfolio and pipeline at ASCO and EHA

PUBLISHED MAY 26, 2022
BY GSK

For media and investors only

- New data evaluating Blenrep (belantamab mafodotin) in combination with standard of care and investigational multiple myeloma therapies to be presented

- Long-term outcomes from the GARNET trial that highlight the impact of Jemperli (dostarlimab) in patients with mismatch repair-deficient (dMMR) recurrent or advanced solid tumours, including endometrial cancer, to be presented

GSK plc will present 25 abstracts at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting (3-7 June) and nine abstracts at the European Hematology Association (EHA) 2022 Hybrid Congress (9-12 June) focusing on approved therapies, Blenrep (belantamab mafodotin), Jemperli (dostarlimab) and Zejula (niraparib), as well as its investigational medicines. The data presentations further demonstrate the company's commitment to evaluate its approved and investigational therapies alone and in combination with other treatments and explore potential opportunities to improve patient care.

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

> We have strategically built a portfolio and pipeline that leverages the science of the immune system, human genetics and advanced technologies to address a variety of tumour types. The data we will be sharing at ASCO and EHA demonstrate how we're delivering on our commitment to patients through novel approaches in some of the most promising areas of oncology research. We look forward to these

important opportunities to come together and to share meaningful scientific updates with the broader oncology community.

Updates from the robust DREAMM clinical trial programme

Key presentations at ASCO and EHA include updates from the DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical trial programme evaluating belantamab mafodotin, an anti-BCMA (B-cell maturation antigen) therapy, in combination with both standard of care and investigational agents in earlier lines of therapy. Preliminary data from DREAMM-5 sub-study 3 of low-dose belantamab mafodotin in combination with nirogacestat in patients with relapsed/refractory multiple myeloma (ASCO abstract #8019) will be reported. Nirogacestat, an investigational gamma secretase inhibitor, has been shown to increase target density and reduce levels of soluble BCMA, and as such the potential to enhance the activity of BCMA-targeted therapies like belantamab mafodotin is under investigation.

DREAMM-6 updates report outcomes from several dose cohorts of belantamab mafodotin in combination with lenalidomide and dexamethasone (Rd) in patients with relapsed/refractory multiple myeloma who have received one or more prior lines of treatment (ASCO abstract #8017).

DREAMM-9, evaluating a quadruplet combination treatment regimen of belantamab mafodotin with standard of care (bortezomib, lenalidomide and dexamethasone or VRd) in patients with newly diagnosed multiple myeloma who are transplant ineligible, will also be presented at EHA (EHA abstract #P942).

Collectively, the data from these trials are evaluating the efficacy and safety of belantamab mafodotin in patients with various lines of therapy, but also aim to assess how dose, scheduling and combination treatment may help to reduce corneal events associated with treatment. These data will be used to help inform further studies evaluating the potential of belantamab mafodotin in the multiple myeloma setting.

Blenrep 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. Studies are ongoing to verify clinical benefit.

Advancing research for patients with mismatch repair-deficient solid cancers

Results from the GARNET trial Cohorts A1 and A2 of dostarlimab, a programmed cell death receptor-1 (PD-1) blocking antibody, in advanced/recurrent (A/R) mismatch repair deficient/microsatellite instability-high or proficient/stable (dMMR/MSI-H or MMRp/MSS) endometrial cancer will be presented during a presentation at ASCO (ASCO abstract #5509). These results include the largest cohort of patients with dMMR A/R endometrial cancer treated with a PD-1 inhibitor monotherapy and will inform long-term use of dostarlimab in this patient population. In addition, long-term outcomes from the GARNET trial Cohorts A1 and F will be shared, covering the efficacy and safety profile of dostarlimab in certain patients with dMMR recurrent or advanced solid tumours, including endometrial cancer (ASCO abstract #2587). Results from Cohort A1 of the GARNET trial served as the basis for conditional approval in the EU for the treatment of certain patients with dMMR/MSI-H recurrent or advanced endometrial cancer, and for the accelerated approval in the US for certain patients with dMMR recurrent or advanced endometrial cancer. Additionally, results from Cohorts A1 and F served as the basis for the accelerated approval in the US for certain patients with dMMR recurrent or advanced solid tumours.

Realising the potential of synthetic lethality

GSK will also present real-world analyses from six studies in patients with advanced ovarian cancer at ASCO, including real-world data evaluating outcomes in patients with advanced ovarian cancer who receive poly (ADP-ribose) polymerase (PARP) inhibitor monotherapy as maintenance compared to those who do not. Insights from the presentations will deepen the understanding of the use of PARP inhibitors for maintenance therapy in advanced ovarian cancer and shed light on differences in treatment practice across geographic locations.

Separately, a phase III PRIME study update will be shared by Zai Lab (a GSK partner) evaluating niraparib (independently manufactured by Zai Lab) in Chinese patients with newly diagnosed advanced ovarian cancer using an individualised starting dose in a poster presentation

(ASCO abstract #5551).

Continued research on immuno-oncology investigational agents

GSK will also present findings from its early-stage pipeline assets, including a poster discussion on the AMBER study evaluating cobolimab, an investigational anti-TIM-3 targeting monoclonal antibody, in combination with dostarlimab in patients with advanced or metastatic melanoma (ASCO abstract #9513). TIM-3 is a key immune checkpoint and a novel immuno-oncology target that could play a critical role in the treatment of solid tumours. GSK is evaluating cobolimab for patients with different tumour types through various novel combinations, including doublets and triplets.

Collaborating to improve patient care

GSK is supporting investigator-sponsored studies and fostering scientific collaborations with both experienced investigators and networks, who are involved in the continuum of care of patients living with cancer. At ASCO, updated data from an investigator-sponsored study from Memorial Sloan Kettering Cancer Center will be featured in a late-breaking oral presentation entitled

> Single agent PD-1 blockade as curative-intent treatment in mismatch repair deficient locally advanced rectal cancer

(ASCO abstract #LBA5). Initial data were presented earlier this year at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI). There will be five additional GSK-supported investigator-sponsored studies presented at ASCO.

At EHA, data from the BelaCarD investigator-sponsored study will report safety, tolerability and preliminary efficacy of belantamab mafodotin in combination with carfilzomib and dexamethasone in patients with relapsed/refractory multiple myeloma (EHA abstract #P946). Additionally, an oral presentation on updated results from a supported collaborative study will evaluate the safety and efficacy of belantamab mafodotin plus lenalidomide and dexamethasone in transplant-ineligible patients with newly diagnosed multiple myeloma (EHA abstract #S178).

Full list of GSK’s presentations at ASCO:

| Abstract Name | Presenter | Presentation Details |

| Comparison of Survival Outcomes Between Dostarlimab and Comparator Treatments (tx) in Patients (pts) with Advanced/Recurrent (A/R) Endometrial Cancer (EC) in England: Matching-Adjusted Indirect Comparisons (MAICs)| S. Goulden | Online publication, #e17534 |

| Dostarlimab in Advanced/Recurrent (AR) Mismatch Repair Deficient/Microsatellite Instability–High or Proficient/Stable (dMMR/MSI-H or MMRp/MSS) Endometrial Cancer (EC): The GARNET Study| A. Oaknin | Clinical Science Symposium presentation, #5509 |

| Efficacy and Safety of Dostarlimab in Patients (pts) with Mismatch Repair Deficient (dMMR) Solid Tumors: Analysis of 2 Cohorts in the GARNET Study| T. André | Poster presentation, #2587 |

| Patient-Reported Outcomes from the GARNET Trial in Patients with Advanced or Recurrent Mismatch Repair Deficient (dMMR) Colorectal Cancer (CRC): A Post Hoc Subgroup Analysis| J. Hanlon | Poster presentation, #3558 |

| Survival Outcomes for Dostarlimab and Real-World (RW) Treatment (tx) Paradigms in Post-Platinum Patients (pts) with Advanced/Recurrent (A/R) Endometrial Cancer (EC): The GARNET Trial versus an External Control Arm from the Flatiron Health Database| R. Coleman | Poster presentation, #5593 |

| Understanding Patient Characteristics, Treatment Patterns, and Clinical Outcomes for Advanced and Recurrent Endometrial Cancer in Alberta, Canada| J. McGee | Online publication, #e17624 |

| Abstract Name | Presenter | Abstract Number |

| Exploring Alternative Dosing Regimens of Single-Agent Belantamab Mafodotin on Safety and Efficacy in Patients with Relapsed or Refractory Multiple Myeloma: DREAMM-14| M. Hultcrantz | Poster presentation, #TPS8073 |

| Safety and Clinical Activity of Belantamab Mafodotin with Lenalidomide Plus Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-6 Arm-A Interim Analysis| H. Quach | Poster discussion, #8017 |

| Safety and Clinical Activity of Belantamab Mafodotin with Pembrolizumab in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-4 Study| A. Suvannasankha | Poster discussion, #8018 |

| Synergistic Effects of Low-Dose Belantamab Mafodotin in Combination with a Gamma-Secretase Inhibitor (Nirogacestat) in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-5 Study| S. Lonial | Poster discussion, #8019 |

| Abstract Name | Presenter | Presentation Details |

| MOONSTONE/GOG-3032: Interim Analysis of a Phase 2 Study of Niraparib + Dostarlimab in Patients (pts) with Platinum-Resistant Ovarian Cancer (PROC)| L. Randall | Poster presentation, #5573 |

| Real-World Trends of PARPi Maintenance Treatment Uptake and Progression-Free Survival (PFS) in Patients (Pts) with Newly Diagnosed Advanced Ovarian Cancer (AOC) in the United States| J. Chan | Poster presentation, #6580 |

| Treatment and Outcome of Patients with High Grade Advanced Ovarian Cancer (AOC) - Real World Data in Germany (QS Ovar of the AGO Study Group)| S. Mahner | Online publication, #e17613 |

| Treatment Patterns and Time to Next Treatment Among Patients with OC in a Real-Life Setting in Finland: The OCRWE-Finland Study| H. Rauhamaa | Online publication, #e18806 |

| Abstract Name | Presenter | Presentation Details |

| AMBER Parts 1C and 1E: A Phase 1 Study of Cobolimab plus Dostarlimab in Patients (pts) with Advanced/Metastatic Melanoma| A. Ribas | Poster discussion, #9513 |

| Phase 1 Trial of TIM-3 Inhibitor Cobolimab Monotherapy and in Combination with PD-1 Inhibitors Nivolumab or Dostarlimab (AMBER)| G. Falchook | Oral presentation, #2504 |

| Primary Efficacy and Safety of Letetresgene Autoleucel (lete-cel; GSK3377794) Pilot Study in Patients with Advanced and Metastatic Myxoid/Round Cell Liposarcoma (MRCLS)| S. D’Angelo | Oral presentation, #11500 |

| Study Design of A Global Molecular Disease Characterization Initiative (MDCI) in Oncology Clinical Trials| D. Downs | Online publication, #e13598 |

| ZENYTH-ESO: Master Protocol to Assess the Safety and Recommended Phase II Dose of Next Generation NY-ESO-1–Specific TCR T-cells in HLA-A*02 Patients with Synovial Sarcoma and Myxoid/Round Cell Liposarcoma [Substudy 3, GSK4427296]| D. Araujo | Poster presentation, #TPS2681 |

Full list of investigator-sponsored studies at ASCO:

| Abstract Name | Presenter | Presentation Details |

| AGO-OVAR 28 / ENGOT-ov57: Niraparib vs Niraparib in Combination with Bevacizumab in Patients with Carboplatin-Taxane Based Chemotherapy in Advanced Ovarian Cancer–A Multicentre Randomised Phase III Trial| F. Heitz | Poster presentation, #TPS5612 |

| A Phase II Study Evaluating the Efficacy of Niraparib and Dostarlimab (TSR-042) in Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma| V. Karivedu | Poster presentation, #TPS6105 |

| A Randomized Phase Ib/II Study of Niraparib (Nira) plus Either Nivolumab (Nivo) or Ipilimumab (Ipi) in Patients (Pts) with Platinum-Sensitive Advanced Pancreatic Cancer (aPDAC)| K. Reiss | Poster discussion, #4021 |

| Results of a Phase II Trial of the PARP Inhibitor, Niraparib, in BAP1 and other DNA Damage Response Pathway Deficient Neoplasms| T. George | Poster presentation, #3122 |

| Role of Cytoreductive Surgery for the Second Ovarian Cancer Relapse in Patients Previously Treated with Chemotherapy Alone at First Relapse: A Subanalysis of the DESKTOP III Trial| J. Sehouli | Poster discussion, #5520 |

| Single Agent PD-1 Blockade as Curative-Intent Treatment in Mismatch Repair Deficient Locally Advanced Rectal Cancer| A. Cercek | Late-breaking oral presentation, #LBA5 |

Full list of GSK’s presentations at EHA:

| Abstract Name | Presenter | Presentation Details |

| DREAMM-9: Phase I Study of Belantamab Mafodotin Plus Standard of Care in Patients with Transplant-Ineligible Newly Diagnosed Multiple Myeloma| S. Usmani | Poster session, #P942 |

| Exploring Alternative Dosing Regimens of Single-Agent Belantamab Mafodotin on Safety and Efficacy in Patients with Relapsed or Refractory Multiple Myeloma: DREAMM-14| M. Hultcrantz | Online publication, #PB2022 |

| Safety and Clinical Activity of Belantamab Mafodotin with Lenalidomide Plus Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-6 Arm-A Interim Analysis| H. Quach | Poster session, #P941 |

| Safety and Clinical Activity of Belantamab Mafodotin with Pembrolizumab in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-4 Study| A. Suvannasankha | Poster session, #P940 |

| Survival Outcomes of Patients with Multiple Myeloma in France: A Cohort Study Using the French National Healthcare Database (SNDS) | X. Leleu | Poster session, #P943 |

| Synergistic Effects of Low Dose Belantamab Mafodotin in Combination with a Gamma-Secretase Inhibitor (Nirogacestat) in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-5 Study| A. Nooka | Poster session, #P939 |

Full list of investigator-sponsored studies at EHA:

| Abstract Name | Presenter | Presentation Details |

| A Phase I/II Single Arm Study of Belantamab Mafodotion, Carfilzomib and Dexamethasone in Patients with Relapsed Multiple Myeloma: AMARC 19-02 BelaCarD Study| M. Lasica | Poster session, #P946 |

| Efficacy and Safety of Belantamab Mafodotin Monotherapy in Patients with Relapsed or Refractory Light Chain Amyloidosis: A Phase 2 Study by the European Myeloma Network| E. Kastritis | Poster presentation, #P914 |

| Safety and Efficacy of Belantamab Mafodotin in Combination with RD

in Newly Diagnosed, Transplant Ineligible Multiple Myeloma Patients: A Phase I/II Study by the Hellenic Society of Hematology| E. Terpos | Oral presentation, #S178 |

Multiple myeloma is the second most common blood cancer in the US and is generally considered treatable, but not curable., In the US, more than 32,000 people are estimated to be diagnosed with multiple myeloma this year and nearly 13,000 people will die from the disease. Research into new therapies is needed as multiple myeloma commonly becomes refractory to available treatments.

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.

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 in the EU.

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 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/en-gb/company/.

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 Q1 Results for 2022 and any impacts of the COVID-19 pandemic.

Eastman S, Shelton C, Gupta I, Krueger J, Blackwell C, Bojczuk P. Synergistic Activity of Belantamab Mafodotin (anti-BCMA immuno-conjugate) with PF-03084014 (gamma-secretase inhibitor) in BCMA-Expressing Cancer Cell Lines. Blood. 2019;134(supplement_1):4401. doi:10.1182/blood-2019-123705.

CA: A Cancer Journal for Clinicians, Vol. 70, Issue 1, Han/Feb 2020 Pages 7-30.

Kazandjian D. Multiple myeloma epidemiology and survival: A unique malignancy. Semin Oncol. 2016;43(6):676–681. doi:10.1053/j.seminoncol.2016.11.004.

SEER Cancer Facts & Figures 2019. Available at: https://seer.cancer.gov/statfacts/html/mulmy.html. Accessed October 2021.

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

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).

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 May 26, 2022. 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-unveils-latest-research-advances-demonstrating-strength-of-its-portfolio-and-pipeline-at-asco-and-eha-1855

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/