GSK announces positive headline results from PERLA, the phase II trial of Jemperli (dostarlimab) plus chemotherapy in patients with metastatic non-squamous non-small cell lung cancer

PUBLISHED OCT 5, 2022
BY GSK

For media and investors only

PERLA is the largest global head-to-head trial of PD-1 inhibitors in this population

COSTAR, the phase II/III trial combining dostarlimab with cobolimab, a TIM-3 antagonist, in advanced NSCLC advances to phase III

GSK plc (LSE/NYSE: GSK) today announced positive headline results of the PERLA phase II trial, which met its primary endpoint of objective response rate (ORR) by Response Evaluation Criteria in Solid Tumours (RECIST) criteria as determined by blinded independent central review. The trial evaluated dostarlimab in combination with chemotherapy versus pembrolizumab in combination with chemotherapy in first-line patients with metastatic non-squamous non-small cell lung cancer (NSCLC). The PERLA phase II trial is a randomised, double-blind trial of 243 patients and is the largest global head-to-head trial of programmed death receptor-1 (PD-1) inhibitors in this population.The trial was not designed to demonstrate superiority.

Full results from the PERLA phase II trial, including the primary endpoint of ORR and the key secondary endpoint of progression-free survival, with results by programmed death ligand-1 (PD-L1) expression subgroups, will be presented at an upcoming scientific meeting.

The safety and tolerability profile of dostarlimab in the PERLA phase II

trial was consistent with previous clinical trials of similar regimens. The most common treatment-emergent adverse reactions were anaemia, asthenia, nausea, constipation, cough, dyspnoea, vomiting, decreased appetite, and neutropenia.

In addition, GSK is also advancing both arms of the COSTAR Lung trial into phase III. The decision follows the recommendation of the Independent Data Monitoring Committee, given that the trial met its pre-specified expansion criteria per protocol. The COSTAR Lung phase III trial is a randomized, open label 3-arm trial comparing cobolimab, an investigational selective anti–TIM-3 monoclonal antibody, plus dostarlimab plus docetaxel to dostarlimab plus docetaxel to docetaxel alone in patients with advanced NSCLC who have progressed on prior anti-PD-(L)1 therapy and chemotherapy.

Hesham Abdullah, Senior Vice President, Global Head of Oncology Development, GSK said:

> These trials support the ambition for dostarlimab to become the backbone of our ongoing immuno-oncology-based research and development programme when used alone and in combination with standard of care and future novel cancer therapies, particularly in patients with currently limited treatment options.

The PERLA phase II trial is a global, randomised, double-blind trial of 243 patients evaluating the efficacy and safety of dostarlimab plus chemotherapy compared to pembrolizumab plus chemotherapy in patients with metastatic non-squamous NSCLC without a known sensitising epidermal growth factor receptor, anaplastic lymphoma kinase, or receptor tyrosine kinase-1 mutation, V600E mutation of the BRAF gene or other genomic mutation for which an approved targeted therapy is available. The primary endpoint was objective response rate of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy assessed by blinded independent central review per RECIST v1.1. Secondary endpoints include investigator-assessed progression-free survival per RECIST v1.1, overall survival, and safety.

The COSTAR Lung trial is a phase II/III global, randomized, open-label trial of 750 patients. The study evaluates the efficacy and safety of cobolimab plus dostarlimab plus docetaxel and dostarlimab plus docetaxel compared to docetaxel in patients with advanced non-squamous and squamous NSCLC whose disease had progressed on

prior therapy with an anti-PD-(L)1 agent and a platinum doublet-based chemotherapy given in combination or in sequence. The study does not include patients with a known sensitizing epidermal growth factor receptor, anaplastic lymphoma kinase, or receptor tyrosine kinase-1 mutation, for which an approved targeted therapy is available. The primary endpoint is overall survival.

About Jemperli (dostarlimab)

Jemperli 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. Jemperli is being investigated in 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. Jemperli is not approved anywhere in the world in combination with chemotherapy in first-line patients with metastatic non-squamous NSCLC or in combination with other agents to treat patients with advanced NSCLC who have progressed on prior anti-PD-(L)1 therapy and chemotherapy.

Jemperli 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: Jemperli (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, commercialization, and manufacturing of each of these Products under the Agreement.

Cobolimab is a monoclonal antibody against the inhibitory T-cell receptor, T-cell immunoglobulin and mucin domain-containing protein 3 (TIM-3), with potential immune checkpoint inhibitory and antineoplastic activities. Cobolimab was discovered by AnaptysBio and TESARO, Inc., under a Collaboration and Exclusive License Agreement signed in March 2014. The collaboration has resulted in three monospecific antibody drugs 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 manufacture 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.

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/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 Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

Press release distributed by Wire Association on behalf of GSK, on Oct 5, 2022. For more information subscribe and follow us.

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