PERLA phase II trial of Jemperli (dostarlimab) plus chemotherapy shows positive results in first-line metastatic non-squamous non-small cell lung cancer

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For media and investors only

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

- Confirmed objective response rate was 46% in patients treated with investigational dostarlimab combination versus 37% in the pembrolizumab combination

- Key secondary endpoint of median progression-free survival was 8.8 months in the dostarlimab treatment arm versus 6.7 months in the pembrolizumab treatment arm

GSK plc (LSE/NYSE: GSK) today announced results from the PERLA phase II clinical trial investigating dostarlimab in combination with chemotherapy versus pembrolizumab in combination with chemotherapy as a first-line treatment for patients with metastatic non-squamous non-small cell lung cancer (NSCLC). Dostarlimab plus chemotherapy achieved very promising results for the primary endpoint of confirmed objective response rate (ORR) as well as for the key secondary endpoint of median progression-free survival (mPFS).

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 patient population. The findings from the primary analysis were presented today at the European Society for Medical Oncology (ESMO) Immuno-Oncology Congress 2022 in Geneva, Switzerland.

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

> The head-to-head data from the PERLA trial showed that dostarlimab combined with chemotherapy provided robust anti-tumour activity in patients with previously untreated metastatic non-squamous non-small cell lung cancer. The positive results from this trial inform our future development plans and highlight the potential for dostarlimab to be our foundational immuno-oncology therapy as a single-agent and in combination with standards of care and novel therapies within our pipeline.

The primary endpoint was overall ORR by Response Evaluation Criteria in Solid Tumours (RECIST) as determined by blinded independent central review (BICR) and was 46% (n=56/121) in the dostarlimab treatment arm versus 37% (n=45/122) in the pembrolizumab treatment arm (difference in ORR: 9.32%; 80% CI: 1.46% to 17.18%).

The key secondary endpoint, mPFS, was 8.8 months (95% CI: 6.7 to 10.4) in the dostarlimab treatment arm versus 6.7 months (95% CI: 4.9 to 7.1) in the pembrolizumab treatment arm (HR 0.70 [95% CI: 0.50 to 0.98]).

The table below summarizes key results across all pre-specified programmed death ligand-1 (PD-L1) expression cohorts, as measured by Tumor Proportion Score (TPS).

| | | mPFS (Investigator Assessed)(95% CI) | | PFS HR | |

| Pre-specified PD-L1 expression cohorts measured by TPS | dostarlimab | pembrolizumab | dostarlimab | pembrolizumab | |

| Overall | 46% | 37% | 8.8 months | 6.7 months | HR 0.70 |

| TPS

| TPS ≥ 1% | 59% | 39% | 10.4 months | 6.1 months | 0.66 |

| TPS 1% to 49% | 50% | 34% | 9.0 months | 5.4 months | 0.67 |

| TPS ≥ 50% | 74% | 48% | 10.4 months | 6.7 months | 0.60 |

Treatment-emergent adverse events (TEAEs) for dostarlimab in the

PERLA phase II trial were consistent with previous trials of similar regimens. The rate of TEAEs was 97% for both the dostarlimab and pembrolizumab treatments arms of the trial. The rate of Grade 3 or higher TEAEs was 59% in the dostarlimab treatment arm and 60% in the pembrolizumab treatment arm. The most common TEAEs were anaemia, asthenia, nausea, constipation, cough, dyspnoea, vomiting, decreased appetite, and neutropenia.

Solange Peters, M.D., Ph.D., Professor and Chair of Medical Oncology, University Hospital of Lausanne, Switzerland and ESMO President, said:

> Understanding the role of immuno-oncology treatments in the NSCLC patient population is a significant goal we're committed to in the oncology community. Despite advancements in treatment options, unmet need persists for health care providers and their patients. The data results presented at ESMO-IO add to the body of evidence of immuno-oncology agents such as dostarlimab and enhance our knowledge in this important area of research.

GSK is also studying dostarlimab in earlier lines of treatment for endometrial cancer and in combination with other therapeutic agents for patients with advanced/metastatic cancers. This research includes the recently announced positive headline RUBY Phase III trial results in patients with primary advanced or recurrent endometrial cancer, as well as the COSTAR Lung phase III trial comparing cobolimab, an investigational anti-TIM-3 targeting 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.

The PERLA phase II trial is a global, randomised, double-blind trial of 243 patients evaluating the efficacy and safety of dostarlimab plus chemotherapy versus 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.

Lung cancer is one of the most commonly diagnosed cancers worldwide, with more than 2 million new cases diagnosed globally in 2020. 1 It is the most common cause of cancer-related death in men and women worldwide, with relatively poor survival outcomes as evidenced by a five-year survival rate of 21%. 2 Approximately 85% of lung cancer cases are NSCLC. 3, 4 NSCLC develops when once-healthy cells in the lungs begin to grow abnormally and form a tumour. When NSCLC spreads, or metastasizes, it can become more difficult treat, resulting in a significant need for new treatment approaches.

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-L1 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.

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 Reference 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

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