GSK to showcase significant scientific advances in renal care at the American Society of Nephrology Kidney Week 2021

PUBLISHED OCT 18, 2021
BY GSK

For media and investors only

- Late-breaking Phase 3 data will provide new evidence for daprodustat as a potential treatment for patients with anaemia due to chronic kidney disease in both dialysis and non-dialysis populations

- Key data will be presented on 5 November 2021 at 10:30am PT/1:30pm ET/5:30pm BST. Discover more information on viewing the presentation.

GlaxoSmithKline (GSK) plc will present eight abstracts at the upcoming American Society of Nephrology Kidney Week 2021, being held virtually from 4-7 November 2021, including new data that advance science and has the potential to deliver significant medical innovation for patients with kidney disease. Data from all five Phase 3 trials of the ASCEND programme for the investigational medicine daprodustat will be presented at the meeting, plus additional data that further advance the important role of BENLYSTA (belimumab) in treating patients with lupus nephritis.

Daprodustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) that is being investigated as a potential treatment for patients with anaemia due to chronic kidney disease (CKD). It is a key specialty medicine within GSK's late-stage R&D pipeline. GSK plans to share a late-breaking presentation of data from the comprehensive Phase 3 ASCEND (Anaemia Studies in Chronic Kidney Disease: Erythropoiesis via a novel prolyl hydroxylase inhibitor Daprodustat) programme providing further insight into these pivotal data following the positive headline results announced in July 2021.

Four presentations at Kidney Week will highlight results from the five

Phase 3 studies that comprise the pivotal ASCEND programme. These data, which include cardiovascular outcomes evidence in non-dialysis (ASCEND-ND) and dialysis (ASCEND-D) patients, plus studies focused on incident dialysis (ASCEND-ID), quality of life measures (ASCEND-NHQ) and (three times per week) dosing regimens (ASCEND-TD), represent the body of evidence for daprodustat that will be used by GSK to engage global regulatory agencies.

Daprodustat is currently approved in Japan as Duvroq for patients with renal anaemia. It is not approved anywhere else in the world.

Additionally, GSK will present data on BENLYSTA for the treatment of lupus nephritis, including healthcare resource utilisation and cost analyses for both lupus nephritis and systemic lupus erythematosus.

GSK will host a virtual investor event to share further information on the ASCEND programme on 7 November 2021 at 1pm EDT/5pm BST. Media are invited to listen in to the event. Please visit the GSK speeches and presentations page for more information and to register.

| Abstract Name | Presenter | Abstract Number | Presentation Format |

| Effects of Daprodustat on Hemoglobin and Quality of Life in Patients With CKD: Results of the ASCEND-NHQ Randomized, Double-blind, Placebo-controlled Trial| K. Johansen | #FR-OR53 | Oral |

| Daprodustat is non-inferior to darbepoetin alfa in treating anemia in incident dialysis patients | A. Singh | #PO0465 | Poster |

| ASCEND-TD: A randomized, double-blind, active-controlled study of daprodustat administered three-times-weekly in hemodialysis patients| D. Coyne | #PO0487 | Poster |

| ASCEND Program: Efficacy and Safety from ASCEND-D and -ND and Overall MACE Finding | A. Singh | #FR-OR66 | Oral |

| Abstract Name | Presenter | Abstract Number | Presentation Format |

| Effects of Belimumab (BEL) on Renal Outcomes in Patients With Relapsed and Newly Diagnosed Active Lupus Nephritis (LN)| H. Anders | #SA-OR32 | Oral |

| Healthcare Costs Associated With Systemic Lupus Erythematosus (SLE) in the Year Prior to Diagnosis of End-Stage Kidney Disease

(ESKD): Real-World Evidence From 2 Databases in the United States (US)| C. Bell | #PO2409 | Poster |

| Healthcare Resource Utilization and Costs Over 5 Years for a Systemic Lupus Erythematosus (SLE) Cohort Newly Diagnosed With Lupus Nephritis: Evidence From a US Administrative Claims Database| C. Bell | #PO1437 | Poster |

| Clinical Outcomes Associated with Systemic Lupus Erythematosus (SLE) in the 5 Years Prior to End-Stage Kidney Disease (ESKD) Diagnosis| C. Bell | #PUB315 | Abstract accepted only (no presentation) |

Chronic kidney disease (CKD), characterised by progressive loss of kidney function, is an increasing global public health burden. Risk factors for CKD include hypertension, diabetes, obesity and primary renal disorders. However, it is often poorly diagnosed and undertreated in patients with early-stage CKD, such as those not on dialysis.

About the ASCEND Programme

The ASCEND programme is comprised of five Phase 3 studies to assess the efficacy and safety of daprodustat for the treatment of anaemia due to chronic kidney disease (CKD) across the CKD disease pathway. The programme enrolled over 8,000 patients who were treated for up to 4.26 years.

The two pivotal trials within the programme are ASCEND-ND and ASCEND-D, which investigated patients with non-dialysis and dialysis, respectively. The ASCEND-ND (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Non-Dialysis) study enrolled 3,872 non-dialysis dependent patients with anaemia associated with CKD who were either switching from or naive to erythropoiesis-stimulating agent (ESA) therapy. The ASCEND-D (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Dialysis) study enrolled 2,964 dialysis-dependent patients with anaemia associated with CKD who were switched to daprodustat or ESA control from a standard of care ESA.

The programme also included studies focused on incident dialysis, for patients just starting dialysis (ASCEND-ID); quality of life measures (ASCEND-NHQ); as well as three times weekly dosing regimens

(ASCEND-TD). The ASCEND-ID (Anaemia Studies in Chronic Kidney Disease: Erythropoiesis Via a Novel Prolyl Hydroxylase Inhibitor (PHI) Daprodustat-in Incident Dialysis) study enrolled 312 patients with anaemia associated with CKD who were not regularly using ESAs and who were initiating dialysis. The ASCEND-NHQ (Anaemia Studies in Chronic Kidney Disease: Erythropoiesis Via a Novel Prolyl Hydroxylase Inhibitor (PHI) Daprodustat in Non-Dialysis Subjects Evaluating Haemoglobin and Quality of Life) study enrolled 614 patients with anaemia associated with CKD who were naïve to ESA treatment. The ASCEND-TD (Anaemia Studies in Chronic Kidney Disease CKD: Erythropoiesis Via a Novel Prolyl Hydroxylase Inhibitor (PHI) Daprodustat-Three-times Weekly Dosing in Dialysis) study enrolled 407 patients with anaemia associated with CKD who were switched to daprodustat or ESA control from a standard of care ESA.

Daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), belongs to a novel class of oral medicines indicated for the treatment of anaemia due to chronic kidney disease in adult patients not on dialysis and on dialysis. Inhibition of oxygen-sensing prolyl hydroxylase enzymes stabilises hypoxia-inducible factors, which can lead to transcription of erythropoietin and other genes involved in the correction of anaemia, similar to the physiological effects that occur in the body at high altitude. Daprodustat has been developed to provide a convenient oral treatment option for patients with anaemia associated with CKD.

GSK is focused on advancing treatment for people with lupus, building on decades of research with a long-term commitment to innovative science. As the only company with a biological treatment approved for both adults with lupus and active lupus nephritis, as well as pediatric lupus, GSK is leading the way to help patients and their families manage this chronic, inflammatory autoimmune disease throughout its course. Our lupus experience stands strong on a wealth of clinical and real-world evidence in the development of BENLYSTA, and as leaders in lupus we are investing and innovating for today and for the future. We understand this disease can affect patients differently and that many have unique needs. We strive for innovative ways to bring treatments to those who need them while actively seeking opportunities to partner with patients, advocates and physicians to inspire long-term goals that will help them feel hopeful for the future.

About BENLYSTA (belimumab)

BENLYSTA, a BLyS-specific inhibitor, is a human monoclonal antibody that binds to soluble BLyS. BENLYSTA does not bind B cells directly. By binding BLyS, BENLYSTA inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells. First approved in 2011, it is the first and only approved biologic for both SLE and LN in more than 50 years.

The following information is based on the US Prescribing Information for BENLYSTA in licensed indications only. Please consult the full Prescribing Information for all the labelled safety information for BENLYSTA.

BENLYSTA is indicated for patients aged ≥5 with active, autoantibody-positive systemic lupus erythematosus (SLE) receiving standard therapy and patients aged ≥18 with active lupus nephritis receiving standard therapy. BENLYSTA is not recommended in patients with severe active central nervous system lupus or in combination with other biologics.

IMPORTANT SAFETY INFORMATION

Previous anaphylaxis with BENLYSTA.

Serious Infections: Serious and sometimes fatal infections have been reported, and occurred more frequently with BENLYSTA. Use caution in patients with severe or chronic infections, and consider interrupting therapy in patients with a new infection.

Progressive Multifocal Leukoencephalopathy (PML): Cases of JC virus-associated PML resulting in neurological deficits, including fatal cases, have been reported. If PML is confirmed, consider stopping immunosuppressant therapy, including BENLYSTA.

Hypersensitivity Reactions (Including Anaphylaxis): Acute hypersensitivity reactions, including anaphylaxis (eg, hypotension, angioedema, urticaria or other rash, pruritus, and dyspnea) and death, have been reported. Generally, reactions occurred within hours of the infusion but may occur later, including in patients who have previously tolerated BENLYSTA. Non-acute hypersensitivity reactions (eg, rash, nausea, fatigue, myalgia, headache, and facial edema) typically occurred up to a week after infusion. Monitor patients during and after treatment and be prepared to manage anaphylaxis; discontinue

immediately in the event of a serious reaction.

Infusion Reactions: Serious infusion reactions (eg, bradycardia, myalgia, headache, rash, urticaria, and hypotension) were reported in adults. If an infusion reaction develops, slow or interrupt the infusion.

Depression and Suicidality: Psychiatric events primarily related to depression, insomnia, anxiety, and suicidality were reported more frequently with BENLYSTA. Before adding BENLYSTA, assess patients' risk of depression and suicide and monitor them during treatment. Instruct patients/caregivers to contact their HCP if they experience new/worsening depression, suicidal thoughts, or other mood changes.

Malignancy: The impact of BENLYSTA on the development of malignancies is unknown; its mechanism of action could increase the risk for malignancies.

Immunization: Live vaccines should not be given for 30 days before or concurrently with BENLYSTA as clinical safety has not been established.

Use With Biologic Therapies: BENLYSTA has not been studied and is not recommended in combination with other biologic therapies, including B-cell targeted therapies.

The most common serious adverse reactions in adult SLE clinical trials were serious infections; some were fatal. The most common adverse reactions (≥5%) were nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, pain in extremity, depression, migraine, pharyngitis, and injection site reactions (subcutaneous injection).

Adverse reactions reported in clinical trials with SLE pediatric patients (≥5 years) and adult patients with lupus nephritis were consistent with those observed in adult SLE trials.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are insufficient data in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. After a risk/benefit assessment, if prevention is warranted, women of childbearing potential should use contraception during treatment and for ≥4 months after the final treatment.

Pregnancy Registry: HCPs are encouraged to register patients and pregnant women are encouraged to enroll themselves by calling 1-877-681-6296.

GSK is a science-led global healthcare company. For further information, please visit www.gsk.com/aboutus.

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.

Hill NR, Fatoba ST, Oke JL, et al. Global prevalence of chronic kidney disease - A systematic review and meta-analysis. PLoS One. 2016;11(7):e0158765.

St Peter WL, Guo H, Kabadi S, et al. Prevalence, treatment patterns, and healthcare resource utilization in Medicare and commercially insured non-dialysis-dependent chronic kidney disease patients with and without anemia in the United States. BMC Nephrol. 2018;19(1):67.

Press release distributed by Wire Association on behalf of GSK, on Oct 18, 2021. For more information subscribe and follow us.

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