GSK announces update on US FDA regulatory review of daprodustat in anaemia of chronic kidney disease

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For media and investors only

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) will convene a meeting of the Cardiovascular and Renal Drugs Advisory Committee to review the New Drug Application (NDA) for daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) under regulatory review for the potential treatment of anaemia due to chronic kidney disease (CKD) in adult patients on dialysis and not on dialysis.

GSK is committed to working closely with the US FDA to bring daprodustat to appropriate patients with anaemia of CKD. A date for the Advisory Committee meeting is set for 26 October 2022.

Chris Corsico, Senior Vice President, Development, GSK said: “We believe daprodustat and the results demonstrated in the ASCEND clinical trial programme have significant potential for patients living with anaemia of CKD who currently do not have an oral treatment option. We look forward to participating in the upcoming Advisory Committee meeting and working with the US FDA to complete its assessment of daprodustat, with the goal of bringing this innovative new treatment to appropriate patients in the US."

The daprodustat NDA is based on positive results from the ASCEND phase III clinical trial programme, which included five pivotal studies assessing the efficacy and safety of daprodustat for the treatment of anaemia across the spectrum of CKD. Results from the key cardiovascular outcomes studies were published in the New England Journal of Medicine in November 2021 and included non-dialysis (ASCEND-ND) and dialysis (ASCEND-D) CKD patients. These studies

demonstrated that daprodustat improved and/or maintained haemoglobin (Hb) within the target level (10-11.5 g/dL), and the primary safety analysis of the intention-to-treat (ITT) populations showed that daprodustat achieved non-inferiority of MACE (major adverse cardiovascular events) compared to the standard of care, an erythropoietin stimulating agent (ESA), across both non-dialysis and dialysis patient settings.

In March 2022, the European Medicines Agency validated the marketing authorisation application for daprodustat, which is currently under regulatory review. Additional regulatory submissions are anticipated to continue throughout 2022. In June 2020, Duvroq (daprodustat) tablets were approved by Japan's Ministry of Health, Labour and Welfare for patients with renal anaemia.

About the ASCEND phase III clinical trial programme

The ASCEND programme includes five phase III studies to assess the efficacy and safety profile of daprodustat for the treatment of anaemia of CKD across the disease spectrum. The programme enrolled over 8,000 patients who were treated for up to 4.26 years.

Results from all five studies were presented at the American Society of Nephrology's Kidney Week 2021. Results from the two pivotal cardiovascular outcomes studies, ASCEND-ND and ASCEND-D, which investigated patients not on dialysis and on dialysis, respectively, were also published in the New England Journal of Medicine,:

ASCEND-ND(Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Non-Dialysis) enrolled 3,872 non-dialysis dependent patients with anaemia of CKD who were either switched from the standard of care (ESA) or not currently receiving ESA therapy to receive daprodustat or ESA control (darbepoetin alfa). Iron management protocols were instituted across both arms of the study. The study met its primary efficacy and safety endpoints. Results showed that daprodustat improved and/or maintained Hb within the target level (10-11.5 g/dL) for these patients, and the primary safety analysis of the ITT population showed that daprodustat achieved non-inferiority of MACE compared to ESA control.

ASCEND-D(Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Dialysis) enrolled 2,964 dialysis patients with anaemia of

CKD who were switched to receive daprodustat or ESA control from a standard of care ESA therapy. A uniform iron management protocol was instituted across both arms of the study. The study met its primary efficacy and safety endpoints. Results showed that daprodustat improved or maintained Hb within target levels (10-11.5 g/dL) for these patients, and the primary safety analysis of the ITT population showed that daprodustat achieved non-inferiority of MACE compared to ESA control.

About anaemia of 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., When left untreated or undertreated, anaemia of CKD is associated with poor clinical outcomes and leads to a substantial burden on patients and healthcare systems.

Daprodustat, a HIF-PHI, belongs to a novel class of oral medicines being studied for the treatment of anaemia of CKD 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 human body at high altitude. Daprodustat is being developed to provide a convenient oral treatment option for patients with anaemia of CKD.

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.

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