Jesduvroq (daprodustat) approved by US FDA for anaemia of chronic kidney disease in adults on dialysis

PUBLISHED FEB 1, 2023
BY GSK

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- Jesduvroq is the only oral HIF-PHI approved in the US, offering adults on dialysis with anaemia of chronic kidney disease a new oral treatment option

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved Jesduvroq (daprodustat), an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the once-a-day treatment of anaemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months. Jesduvroq is the first innovative medicine for anaemia treatment in over 30 years and the only HIF-PHI approved in the US, providing a new oral, convenient option for patients in the US with anaemia of CKD on dialysis.

Tony Wood, President and Chief Scientific Officer, GSK, said:

> Over the last several decades, there has been little innovation in anaemia of CKD. We are proud to have developed Jesduvroq as a new oral treatment where there is a patient desire for more options.

The FDA approval is based on results from the ASCEND-D trial, assessing the efficacy and safety of Jesduvroq for the treatment of anaemia of CKD in patients on dialysis. Results were published in the New England Journal of Medicine with additional results (PDF - 3,472KB) published in the New England Journal of Medicine

supplementary appendix.

CKD is an increasing global health burden affecting 700 million patients worldwide, with an estimated one in seven patients also developing anaemia. 1, 2 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. 3 There is an unmet need for oral treatment options with efficacy and safety comparable to current treatments.

LaVarne Burton, President and Chief Executive Officer, American Kidney Fund, said:

> Anaemia of CKD can be a debilitating condition that is challenging to manage. This news means that patients on dialysis who are living with anaemia of CKD now have another treatment option to help manage their anaemia.

A marketing authorisation application for daprodustat is currently under review with the European Medicines Agency, with a regulatory decision anticipated in the first half of 2023. In June 2020, daprodustat tablets were approved by Japan's Ministry of Health, Labour and Welfare for the treatment of patients with anaemia of CKD. In Japan, the brand name for daprodustat is Duvroq, where it is the market leader and preferred HIF-PHI.

About Jesduvroq (daprodustat)

Jesduvroq, a HIF-PHI, belongs to a novel class of oral medicines for the treatment of anaemia of CKD in adult patients 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. 4, 5 Jesduvroq provides an oral treatment option for adult patients with anaemia of CKD on dialysis. 6 Jesduvroq is a tablet available in 5 dosage strengths: 1mg, 2mg, 4mg, 6mg, 8mg.

About the ASCEND Phase III clinical trial programme

The ASCEND programme included five Phase III trials 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 trials were presented at the American Society of Nephrology's Kidney Week 2021.

Results from the pivotal cardiovascular outcomes trial, ASCEND-D, which investigated patients on dialysis, were published in the New England Journal of Medicine: 6

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 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 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 is characterised by progressive loss of kidney function. 7 Anemia is an important and frequent complication of CKD and is associated with increased morbidity, mortality and reduced quality of life. 8 It is often poorly diagnosed and undertreated in patients with early-stage CKD. 9 Over 700 million patients suffer from CKD worldwide, and an estimated 1-in-7 of these patients have anaemia. 1, 2 CKD affects approximately 39 million people in the US, of whom approximately 6 million are also affected by anaemia. 1, 2 There are approximately 810,000 patients who are end-stage renal disease (ESRD) in the US. 10 Of which, there are 558,000 patients receiving dialysis. 3

Please consult the full Prescribing Information including Boxed Warning and Medication Guide.

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 Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

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Press release distributed by Wire Association on behalf of GSK, on Feb 1, 2023. For more information subscribe and follow us.

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