GSK announces positive headline results from five Phase 3 studies of daprodustat for patients with anaemia due to chronic kidney disease

PUBLISHED JUL 16, 2021
BY GSK

For media and investors only

Issued: London UK – LSE announcement

Full results to be presented at a medical meeting later this year

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced positive headline results from five studies of the Phase 3 ASCEND programme, evaluating the efficacy and safety profile of daprodustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for patients with anaemia due to chronic kidney disease (CKD).

The ASCEND programme showed that daprodustat met its primary efficacy endpoint in each study, demonstrating an improvement in haemoglobin (Hgb) levels in untreated patients and maintaining Hgb levels in patients treated with an erythropoietin stimulating agent (ESA), a standard treatment option, in patients with anaemia of CKD. In addition, the key cardiovascular outcomes studies for non-dialysis (ASCEND-ND) and dialysis patients (ASCEND-D) demonstrated that daprodustat was non-inferior when compared to an ESA in the risk of Major Adverse Cardiovascular Events (MACE), the co-primary endpoint of both studies.

Dr. Hal Barron, Chief Scientific Officer and President R&D, GSK, said:

> I am particularly pleased with the results from the ASCEND-ND and ASCEND-D studies given the importance of managing cardiovascular outcomes for patients who are currently

suffering from anaemia due to chronic kidney disease, as well as the need to provide a convenient, oral treatment option. We will continue to analyse the data from the robust phase 3 ASCEND programme and look forward to working closely with regulators as we plan for our submissions.

In addition to the ASCEND-D and ASCEND-ND studies, 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). Each of the studies from the programme met its respective primary or co-primary endpoint(s). The programme enrolled over 8,000 patients who were treated for up to 3.75 years. The full results of the studies will be presented at a forthcoming medical meeting later this year and will be used to inform regulatory pathways with health authorities worldwide.

Across the ASCEND programme, daprodustat was generally well tolerated in both non-dialysis and dialysis patients. The incidence of treatment-emergent adverse events was similar between treatment groups and the nature of reported events was consistent with the underlying patient population. The most commonly reported adverse events in patients receiving daprodustat across the ASCEND programme included hypertension, diarrhoea, dialysis hypotension, peripheral edema, and urinary tract infection.

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

Chronic kidney disease, 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.

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 a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

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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.

Wong MMY, Tu C, Li Y, et al. Anemia and iron deficiency among chronic kidney disease stages 3–5 ND patients in the Chronic Kidney Disease Outcomes and Practice Patterns Study: often unmeasured, variably treated. Clin Kidney J. 2019. doi: 10.1093/ckj/sfz091

Hoshino J, Muenz D, Zee J, et al. Associations of hemoglobin levels with health-related quality of life, physical activity, and clinical outcomes in persons with stage 3-5 nondialysis CKD. J Ren Nutr. 2020.

Toft G, Heide-Jorgensen U, van Haalen H, et al. Anemia and clinical outcomes in patients with non-dialysis dependent or dialysis dependent severe chronic kidney disease: a Danish population-based study. J Nephrol. 2020;33(1):147–156.

Locatelli F, Pisoni RL, Combe C, et al. Anaemia in haemodialysis patients of five European countries: association with morbidity and

mortality in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2004;19(1):121–132.

Hayashi T, Uemura Y, Kumagai M, et al. Effect of achieved hemoglobin level on renal outcome in non-dialysis chronic kidney disease (CKD) patients receiving epoetin beta pegol: MIRcerA CLinical Evidence on Renal Survival in CKD patients with renal anemia (MIRACLE-CKD Study). Clin Exp Nephrol. 2019;23(3):349–361.

Walker AM, Schneider G, Yeaw J, et al. Anemia as a predictor of cardiovascular events in patients with elevated serum creatinine. J Am Soc Nephrol. 2006;17(8):2293–2298.

Eriksson D, Goldsmith D, Teitsson S, et al. Cross-sectional survey in CKD patients across Europe describing the association between quality of life and anaemia. BMC Nephrol. 2016;17(1):97.

van Haalen H, Jackson J, Spinowitz B, et al. Impact of chronic kidney disease and anemia on health-related quality of life and work productivity: analysis of multinational real-world data. BMC Nephrol. 2020;21(1):88.

Eriksson D, Teitsson S, Goldsmith D, et al. Cross-sectional descriptive study of the impact of anaemia in patients with chronic kidney disease on healthcare resource utilisation and work productivity across Europe. Value Health. 2015;18(A514).

Press release distributed by Wire Association on behalf of GSK, on Jul 16, 2021. For more information subscribe and follow us.

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