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Redx Pharma plc
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REDX PHARMA PLC

("Redx" or the "Company")

Redx Unveils Preclinical Data from New Development Candidate, RXC009, a Novel, Selective Discoidin Domain Receptor 1 Inhibitor

Data from translational disease models supports development of RXC009 as a potential first-in-class treatment for chronic kidney disease

Alderley Park, UK, 6 November 2023 Redx (AIM:REDX), the clinical-stage biotechnology company focused on discovering and developing novel, small molecule, targeted therapeutics for the treatment of fibrotic disease and cancer announces preclinical data for RXC009, a recently nominated development candidate from its Discoidin Domain Receptor (DDR) programme, was presented at the American Society for Nephrology (ASN) Annual Meeting (2-5 November 2023, Philadelphia, US).

RXC009, a small molecule, orally available, highly potent and selective DDR1 inhibitor, was nominated as a development candidate in October 2023 and has potential to be a first-in-class treatment option for chronic kidney disease (CKD) including kidney fibrosis associated with CKD as seen in Alport Syndrome. DDRs have recently gained traction as druggable targets with the potential to treat multiple fibrotic conditions, however to date, no selective inhibitors of DDR1 have entered the clinic.

RXC009 demonstrated excellent selectivity for DDR1 compared to other disclosed DDR inhibitors when tested against kinase and other target panels with limited off-target pharmacology. In a therapeutic unilateral ureteral obstruction (UUO) murine model of kidney fibrosis, RXC009 treatment resulted in a significant reduction in histological markers of both inflammation and fibrosis. Target engagement was also demonstrated in this model with a 72% reduction in phospho-DDR1 (p-DDR1). RXC009 has a favourable absorption, distribution, metabolism and excretion (ADME) and safety profile with a Drug-Drug Interaction (DDI) assessment completed confirming its suitability for potential use in combination. These data further validate the hypothesis that selective inhibition of DDR1 represents an attractive approach for investigation towards the development of new treatments for CKD and taken collectively, supports progressing RXC009 into IND-enabling studies.

Richard Armer, Chief Scientific Officer, Redx Pharma, commented: *"This compelling preclinical data suggests that our selective DDR1 inhibitor, RXC009, has the potential to be a first-in-class treatment with an initial indication in chronic kidney disease and associated fibrosis, which remains a significant unmet medical need. The nomination of our 10th development candidate again highlights our medicinal chemistry expertise and unique ability to develop novel drug candidates against historically challenging disease targets."*

As previously announced, the Company intends to partner its DDR programme for further development as it focuses on advancing its differentiated ROCK portfolio through clinical development.

About CKD and Alport Syndrome

CKD affects 8% to 16% of the population worldwide and is most commonly attributed to diabetes and hypertension. Renal fibrosis, characterised by tubulointerstitial fibrosis and glomerulosclerosis, is one of the final manifestations of CKD as it progresses and is associated with high morbidity¹.

Alport Syndrome is an inherited disease that damages the tiny blood vessels in the kidneys and can lead to kidney disease and kidney failure. There is no specific approved treatment for Alport Syndrome, with current standard of care aiming to treat the symptoms and help slow the progression of kidney disease². While there are no reliable prevalence studies available, Alport Syndrome is estimated to affect less than 200,000 people in the U.S.³, making it a rare disease.

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About Redx Pharma Plc

Redx Pharma (AIM: REDX) is a clinical-stage biotechnology company focused on the discovery and development of novel, small molecule, targeted therapeutics for the treatment of fibrotic disease, cancer and the emerging area of cancer-associated fibrosis, aiming initially to progress them to clinical proof of concept before evaluating options for further development and potential value creation. The Company's lead fibrosis product candidate, the selective ROCK2 inhibitor, zelasudil (RXC007), is in development for interstitial lung disease and is undergoing a Phase 2a trial for idiopathic pulmonary fibrosis (IPF) with topline data expected in H1 2024. The Company's second fibrosis candidate, RXC008, a GI-targeted ROCK inhibitor for the treatment of fibrostenotic Crohn's disease, is progressing towards a CTA application during the fourth quarter of 2023. Redx's lead oncology product candidate, the Porcupine inhibitor RXC004, being developed as a targeted treatment for Wnt-ligand dependent cancers, is expected to report anti-PD-1 combination Phase 2 data during the first half of 2024, following which Redx will seek a partner for ongoing development. In October 2023, Redx nominated its next development candidate, RXC009 a highly potent and selective DDR1 inhibitor for the treatment of chronic kidney disease and associated fibrosis.

The Company has a strong track record of discovering new drug candidates through its core strengths in medicinal chemistry and translational science, enabling the Company to discover and develop differentiated therapeutics against biologically or clinically validated targets. The Company's accomplishments are evidenced not only by its wholly-owned clinical-stage product candidates and discovery pipeline, but also by its strategic transactions, including the sale of pirtobrutinib (RXC005, LOXO-305), a non-covalent (reversible) BTK inhibitor now approved by the US FDA for adult patients with mantle cell lymphoma previously treated with a covalent BTK inhibitor, and AZD5055/RXC006, a Porcupine inhibitor targeting fibrotic diseases including IPF, which AstraZeneca is progressing in a Phase 1 clinical study. In addition, Redx has forged collaborations with Jazz Pharmaceuticals, which includes JZP815, a pan-RAF inhibitor developed by Redx which Jazz is now progressing through Phase 1 clinical studies, and an early-stage oncology research collaboration.

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1. Taken in part from Chen TK et al; [JAMA. 2019 Oct 1; 322\(13\): 1294-1304](https://doi.org/10.1093/jama/2019.10.1).
2. <https://www.kidney.org/atoz/content/alport>
3. <https://alportsyndrome.org/about-alport-syndrome/>

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