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Redx Pharma plc
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REDX PHARMA PLC

("Redx" or the "Company")

Zelasudil granted FDA Orphan Drug Designation

Alderley Park, UK, 21 August 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 that zelasudil (RXC007), an oral, selective Rho Associated Coiled-Coil Containing Protein Kinase 2 (ROCK2) inhibitor, has received Orphan Drug Designation from the US Food and Drug Administration (FDA) for the potential treatment of Idiopathic Pulmonary Fibrosis (IPF). Zelasudil is currently in a Phase 2a clinical study for IPF, with topline data expected in Q1 2024.

The FDA can grant Orphan Drug Designation to support the development and evaluation of new treatments to prevent, diagnose or treat a rare disease or condition that affects fewer than 200,000 in the US. The designation provides Redx with various development and commercial incentives, including market exclusivity, in order to address this unmet need for patients suffering from IPF.

Dr Jane Robertson, Chief Medical Officer, Redx Pharma commented: "We are delighted that the FDA has recognised the potential of zelasudil for the treatment of IPF and granted Orphan Drug Designation. Selectively targeting ROCK2 is an exciting, novel approach which could provide a new treatment option for patients with IPF, and with potential applications in other interstitial lung diseases and cancer-associated fibrosis. We are encouraged by both the strength of our preclinical package as well as the clinical results to date and we look forward to reporting Phase 2a topline data in Q1 2024."

About zelasudil (RXC007)

Zelasudil is an orally available, highly selective small molecule inhibitor that targets ROCK2 which sits at a nodal point in a cell signalling pathway, believed to be central to fibrosis. ROCK2 selectivity is important to avoid systemic hypotension, a serious cardiovascular side effect which has been seen in product candidates that systemically inhibit both ROCK1 and ROCK2. As a selective ROCK2 inhibitor zelasudil, has the potential to treat several fibrotic diseases and has demonstrated robust anti-fibrotic effects in a range of industry-standard *in vivo* preclinical models, results of which were presented at the International Colloquium on Lung and Airway Fibrosis (ICLAF) and the Antifibrotic Drug Development Summit (AFDD) in 2022. Redx is evaluating zelasudil initially as a treatment for IPF, a severe and life-threatening chronic lung condition with limited treatment options.

About IPF

IPF is a debilitating disease of the lungs which progressively causes scarring and a reduction in lung function. Occurring primarily in older adults (>50 years old), it involves irreversible and variable scarring, stiffening, and thickening of the lung tissues, leading to patients experiencing shortness of breath and lack of oxygen absorption. Over 170,000 patients suffer with IPF[1] and around a further 53,000 people are diagnosed each year (US, 5 EU, Japan). Patients diagnosed with IPF have an estimated life expectancy of 3 to 5 years[2]. There is no known cure and current treatment only slows progression of the 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 commenced a Phase 2a trial for idiopathic pulmonary fibrosis (IPF) in October 2022, with topline data expected in Q1 2024. 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 combination with anti-PD-1 Phase 2 data during 2023. Redx's third drug candidate, RXC008, a GI-targeted ROCK inhibitor for the treatment of fibrostenotic Crohn's disease, is progressing towards a CTA application at the end of 2023.

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 two wholly-owned clinical-stage product candidates and rapidly expanding 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] Patient numbers (diagnosed prevalence) & market size forecast data sourced from Global Data (US, EU5, Japan)

[2] Clinical Estimates from Hyun 2015, Ley 2012, Raghu 2006

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