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REDX PHARMA PLC

("Redx" or the "Company")

Redx Provides Progress Update on RXC007 Clinical Programme

Actively recruiting patients in multiple sites across five European countries

US recruitment in 28-day cohort ongoing, longer-term dosing under partial clinical hold pending additional non-clinical data reporting during 2023

Topline Phase 2a data expected in Q1 2024

Alderley Park, UK, 9 February 2023 Redx (AIM:REDX), the clinical-stage biotechnology company focused on discovering and developing novel, small molecule, highly targeted therapeutics for the treatment of cancer and fibrotic disease, announces a progress update on lead fibrosis candidate RXC007. RXC007 is an oral, selective Rho Associated Coiled-Coil Containing Protein Kinase 2 (ROCK2) inhibitor which is currently being assessed in a Phase 2a study in idiopathic pulmonary fibrosis (IPF).

The Phase 2a IPF study is a multi-cohort, randomised, double-blind, placebo-controlled dose ranging study to assess safety and tolerability over a 12-week dosing period, as well as early signals of efficacy. In parallel, the study incorporates a translational science sub-study to evaluate target engagement and fibrosis modification over a 28-day dosing period.

Following the announcement on 11 October 2022 of first patient enrolment in the trial, regulatory and ethics approvals for both the 28-day and the 12-week cohorts have been received in five countries across Europe, and recruitment is progressing at a number of study sites. Additionally, there is an open IND in the US and study sites are currently being initiated, allowing enrolment into the 28-day translational science sub-study. US enrolment into the 12-week cohorts of the study has not commenced and is currently under an FDA partial clinical hold pending the data readout from an ongoing non-clinical programme. The requested data, at clinically relevant doses, is expected later this year and Redx believe will support the longer dosing duration. Ongoing US site set up and enrolment into the 28-day cohort is unaffected.

Overall, based on the current patient recruitment rate, topline data from this Phase 2a study are expected to be available in Q1 2024.

Lisa Anson, Chief Executive Officer, Redx Pharma, commented, *"We are pleased to be actively recruiting our Phase 2a IPF study in both Europe and the US, putting us in a position to report topline data from both the 12-week and 28-day cohorts in Q1 2024. We expect our ongoing non-clinical programme to provide the data during 2023 to address the FDA request and support longer term dosing in the US. We have strong capabilities in creating next-generation products - as shown by our discovery of a next-generation BTK inhibitor - and we are excited about the potential of our next-generation ROCK2 inhibitor, RXC007, to treat a range of fibrotic conditions where there exists a significant unmet medical need."*

ROCK2 inhibition is now a commercially validated target with potential in multiple disease areas, following the recent FDA approval and launch of the first drug with this mechanism of action for the treatment of chronic graft versus host disease (cGvHD). In addition to the ongoing clinical development plan in IPF, Redx has also generated

consistently supportive preclinical data that highlights the broad potential of next-generation ROCK2 inhibitors across a number of fibrotic indications where there remains a significant unmet need. Redx recently presented proof-of-concept data at the International Colloquium on Lung and Airway Fibrosis (ICLAF)[1] that detailed development work in immune mediated models of cGvHD, where the underlying disease mechanisms that drive pathology in the model show similarities to those observed in the lung pathology of auto-immune driven fibrotic diseases such as systemic sclerosis and interstitial lung disease (ILD). Furthermore, encouraging data from an ongoing collaboration with the Garvan Institute of Medical Research, presented at the Antifibrotic Drug Development Summit (AFDD)[2], has shown the potential of Redx's ROCK2 inhibitors in cancer-associated fibrosis, such as that seen in pancreatic cancer. Redx plans to provide updates on further development as appropriate.

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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, highly targeted therapeutics for the treatment of cancer and fibrotic disease 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 RXC007, is in development for interstitial lung disease and commenced a Phase 2a trial for idiopathic pulmonary fibrosis (IPF) in October 2022. Redx's lead oncology product candidate, the Porcupine inhibitor RXC004, being developed as a targeted treatment for Wnt-ligand dependent cancers, commenced a Phase 2 programme in November 2021. Redx's third drug candidate, RXC008, a GI-targeted ROCK inhibitor for the treatment of fibrostenotic Crohn's disease, is progressing towards a CTA/IND 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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About the RXC007 Phase 2a Clinical study in IPF
The Phase 2a study is a 12-week multi-cohort, randomised, double-blind, placebo-controlled dose ranging study to assess early signals of efficacy as well as the safety and tolerability of RXC007 in IPF patients. Both treatment-naïve patients and patients already on approved IPF therapy will be included in the study. Key endpoints for the study will be safety and pharmacokinetic profile; changes from baseline in lung function of forced vital capacity (FVC) and carbon monoxide diffusion coefficient (DLCO); and changes from baseline in Quantative Lung Fibrosis Score (QLFS), airway volume and resistance on high resolution computerised tomography (HRCT) scan.

In the study three dose escalation cohorts of 16 patients will be assigned a dosing period of three months, with patients potentially continuing for longer if they are seen to be tolerating their assigned treatment and there are no signs of disease progression.

As part of the study, a 28-day translational science sub-study will commence in parallel to evaluate target engagement and disease interaction. Endpoints for this sub-study will include changes from baseline in blood biomarkers, proteins and genes from broncho-alveolar lavage (BAL) fluid, BAL-fluid cells and bronchial epithelial cells.

1. https://www.redxpharma.com/wp-content/uploads/2022/10/RXC007_ICLAF_Poster_2022-10-01_FINAL-1.pdf
2. https://www.redxpharma.com/wp-content/uploads/2023/02/RXC007_ROCK2_AFDD_11Nov2022_FINAL.pdf

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