RNS Number : 6955E
Redx Pharma plc
28 February 2024

REDX PHARMA PLC

("Redx" or the "Company")

First Participant Dosed in Phase 1 Clinical Trial for RXC008

Potential first-in-class GI-targeted ROCK inhibitor for fibrostenotic Crohn's disease enters Phase 1 study

RXC008 is the second wholly-owned asset from Redx's ROCK portfolio to enter clinical development

Alderley Park, UK, 28 February 2024 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 today announces that the first participant has been dosed in a Phase 1 clinical trial for RXC008. RXC008 is a wholly-owned gastro-intestinal (GI) targeted Rho Associated Coiled-Coil Containing Protein Kinase (ROCK) inhibitor, being developed as a potential first-in-class treatment for patients with fibrostenotic Crohn's disease. The primary objective of this first-in-human study is to evaluate the safety and pharmacokinetic (PK) profile of the drug and it is expected that results from the healthy volunteer cohorts will be available by the end of 2024.

Lisa Anson, Chief Executive Officer, Redx Pharma commented: "We are delighted to confirm that the first participant has been dosed in the RXC008 Phase 1 clinical study. RXC008 is a potential first-in-class treatment for patients with fibrostenotic Crohn's disease, a debilitating condition where successive surgeries are the only treatment option available today. This milestone represents the sixth asset from Redx to enter clinical development, continuing our strong track record in small molecule drug discovery as a result of our world-class medicinal chemistry and translational science expertise."

Dr Helen Timmis, Interim Chief Medical Officer, Redx Pharma commented: "Fibrostenotic Crohn's disease patients face a significant unmet clinical need and I am pleased that we have successfully progressed RXC008 into the clinic. The strength of our preclinical package makes us hopeful that RXC008 can be a potential first-in-class therapeutic treatment option for fibrostenotic Crohn's patients, and we look forward to reporting the Phase 1 healthy volunteer data later this year."

Fibrostenotic Crohn's disease is a chronic condition that causes inflammation and fibrotic stricture formation in the GI-tract. Over 50% of patients diagnosed with Crohn's disease will develop fibrostenosis within 10 years of diagnosis. There are currently no drugs specifically approved for the underlying fibrosis, which can progress despite intervention with anti-inflammatory therapies. The only current treatment options are invasive surgical procedures to remove the affected part of the GI-tract with the majority of patients requiring many successive surgical interventions.

Phase 1 clinical study overview

The Phase 1 clinical study consists of two parts. The first in healthy volunteers includes both single ascending dose (SAD) and multiple ascending dose (MAD) cohorts, the latter being dosed for 14 days. The primary endpoint for the healthy volunteer cohorts will be safety, with secondary endpoints being related to RXC008's PK profile. The second part of the study will investigate patients with fibrostenotic Crohn's disease who will be dosed for a one-month duration with a placebo control, to show safety along with PK profile, target engagement and changes in circulating biomarkers. Data from the healthy volunteer cohorts are expected to be available by the end of 2024.

About RXC008

RXC008 is a potent, oral, small molecule non-systemic ROCK 1/2 inhibitor that avoids the significant cardiovascular side effects of pan-ROCK inhibitors, including tachycardia and hypotension, by being restricted to the GI-tract via high efflux and low permeability. This results in virtually no systemic breakthrough, with the molecule being rapidly metabolised by paraoxonase enzymes in the plasma should any breakthrough occur under particular circumstances.

RXC008 has a strong preclinical package across multiple therapeutic models, data from which was presented at the 2022 Inflammatory Bowel Disease (IBD) Nordic Conference, including results from a therapeutic 12-week DSS model with a closely related GI-targeted ROCK inhibitor, REDX08087. In this model Redx was able to show complete reversal of preformed GI-fibrosis as measured by trichome collagen staining, fully reversing fibrosis back to baseline levels. This level of anti-fibrotic effect is the strongest seen in any of Redx's fibrosis models and modes of action to date. RXC008 is being developed to be used in conjunction with anti-inflammatories and other symptomatic treatments for Crohn's to address the underlying fibrosis of the disease.

For further information, please contact:

Redx Pharma Plc T: +44 (0)1625 469 918
UK Headquarters
Caitlin Pearson, Head of Communications
ir@redxpharma.com

SPARK Advisory Partners (Nominated Adviser) T: +44 (0)203 368 3550
Matt Davis/ Adam Dawes

WG Partners LLP (Joint Broker) T: +44 (0)203 705 9330
Claes Spång/ Satheesh Nadarajah/ David Wilson

Panmure Gordon (UK) Limited (Joint Broker) T: +44 (0)207 886 2500
Rupert Dearden/ Freddy Crossley/ Emma Earl

FTI Consulting T: +44 (0)203 727 1000
Simon Conway/ Ciara Martin

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. Redx aims to progress its programmes 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 in Phase 1 development with healthy volunteer data expected by the end of 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 anti-PD-1 combination Phase 2 data during the first half of 2024, following which Redx will seek a partner for ongoing development.

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, which include the sale of pirtobrutinib (RXC005, LOXO-305, a non-covalent or reversible. BTK inhibitor) now approved by the US FDA and transactions with both AstraZeneca and Jazz Pharmaceuticals.

To subscribe to Email Alerts from Redx, please visit: www.redxpharma.com/investor-centre/email-alerts/.

may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

END

MSCLDLLLZLLBBBZ