

REDX PHARMA LIMITED

("Redx" or the "Company")

Redx announces presentation of positive Phase 1 results from clinical trial with RXC008, a potential first-in-class treatment for fibrostenotic Crohn's disease

Orally administered pan-ROCK inhibitor was demonstrated to be well-tolerated and safe in this healthy participant study

Importantly, RXC008 exposure was confirmed to be present in predicted efficacious concentrations in GI-tissue with negligible systemic exposure

A Phase 2 study is being planned for H2 2025

Alderley Park, UK, 24 February 2025 [Redx Pharma](#) (JPJ:REDX), the clinical-stage, small molecule biotechnology company, today announces the presentation of results from a RXC008 Phase 1 clinical trial by lead investigator, Dr Florian Rieder, Vice Department Chair, Co-Section Director Inflammatory Bowel Diseases, Director Cleveland Clinic Program for Global Translational Inflammatory Bowel Diseases, Cleveland Clinic, USA, at the 20th Congress of European Crohn's and Colitis Organisation Conference (ECCO), Friday February 21, 2025, Berlin, Germany.

RXC008 is a highly potent pan-Rho-associated coiled kinase (pan-ROCK) inhibitor that was designed to be restricted to the gastrointestinal (GI) tract. The Phase 1 study aimed to assess the safety, tolerability, local and systemic exposure of RXC008 in healthy participants as part of a clinical development program for intestinal fibrosis, such as that associated with Crohn's disease.

The study demonstrated that RXC008 was well tolerated with no safety signals at any tested dose (up to 1000mg as a single oral dose and up to 300mg dosed daily over 14 days) with no adverse events (AEs) reported in the single ascending dose (SAD) study. In the multiple ascending dose (MAD) study, all AEs were mild or moderate with no trends observed. There were no serious adverse events and no AEs leading to treatment discontinuation. Importantly, no hypotension or tachycardia (known liabilities of systemic pan-ROCK inhibition) were observed in any participant.

Robust data was generated during the study that confirmed the drug to be gut-restricted. Minimal systemic exposure was observed even at daily RXC008 doses of 300mg, when predicted efficacious concentrations of RXC008 were detected in

tissue samples obtained from healthy participants ileum and colon via ileocolonoscopy at Day 14 during the MAD section of the trial.

Dr Florian Rieder, M.D., Vice Department Chair, Co-Section Director Inflammatory Bowel Diseases, Director Cleveland Clinic Program for Global Translational Inflammatory Bowel Diseases, Cleveland Clinic, USA, said: *“RXC008 demonstrates the first-in-class potential for a novel treatment for fibrostenotic Crohn’s disease. Anti-inflammatories may suppress inflammation but do not treat the underlying fibrosis, leaving patients with invasive endoscopic or surgical interventions as their only therapeutic option. This is an exciting potential new therapeutic option for an underserved population.”*

Dr Helen Timmis, Interim Chief Medical Officer at Redx Pharma added: *“We are excited to deliver the results of the Phase 1 healthy participant study for intestinal fibrosis. We have now demonstrated that oral administration of RXC008 is safe and well tolerated with exposure in the relevant GI-tissue and minimal systemic exposure. This is a great step forward in the management of Crohn’s disease and we look forward to the start of our Phase 2 study later this year.”*

A copy of the abstract presentation deck is available on the Company website at: <https://www.redxpharma.com/scientific-publications>.

Phase 1 clinical study overview

The Phase 1 clinical study consisted of a single ascending dose (SAD) followed by a multiple ascending dose (MAD) study. In the SAD, 6 cohorts were randomised 2:1 to single oral doses of RXC008 or placebo between 10 and 1000mg. In the MAD, 3 cohorts were randomised 3:1 to RXC008 or placebo daily, at doses of 30, 100 and 300mg, for 14 days. Safety, tolerability and systemic exposure were assessed in both parts. 24-hour blood pressure monitoring and telemetry were used to evaluate hypotensive effects in the SAD and in the first cohort of the MAD. MAD participants underwent Day 14 ileocolonoscopy to assess tissue drug concentrations in biopsies from the ileum and colon.

About ROCK inhibition and RXC008

Rho-associated coiled-coil forming protein kinase (ROCK) is well established as an anti-fibrotic target and is known to consist of two isoforms ROCK 1 and 2. RXC008 is a potent, oral, small molecule non-systemic ROCK1/2 inhibitor that avoids the significant cardiovascular side effects of systemic 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.

About Crohn's disease

Crohn's disease affects 1.7mⁱ people globally and >70,000 new cases are diagnosed each year. More than 50% of patientsⁱⁱ with Crohn's disease can develop significant fibrosis and stricture formation within ten years after diagnosis; this fibrosis associated with Crohn's disease is known as fibrostenotic Crohn's disease. The current management of fibrotic strictures of the gastrointestinal tract is primarily surgical as no drugs are specifically approved for fibrosis, which can progress despite intervention with anti-inflammatory therapies.

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About Redx Pharma Limited

Redx Pharma (JPJ: 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. Redx aims to progress its programmes to clinical proof of concept before evaluating options for further development and potential value creation. The Company is currently progressing an industry leading ROCK inhibitor portfolio through the clinic, including zelasudil, a selective ROCK2 inhibitor for the treatment of interstitial lung diseases including idiopathic pulmonary fibrosis and RXC008, a GI-restricted pan-ROCK inhibitor for the treatment of fibrostenotic Crohn's disease. Additionally, the Company has a Phase 2 precision oncology programme which it intends to partner for further 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. To date, six Redx discovered molecules have been progressed into the clinic with the Company's accomplishments evidenced not only by its wholly-owned clinical-stage product candidates and discovery pipeline, but also by its strategic transactions, which includes the sale of pirtobrutinib (RXC005, LOXO-305), the only non-covalent or reversible BTK inhibitor now approved by the US FDA, and transactions with both AstraZeneca and Jazz Pharmaceuticals.

ⁱ Clarivate, Crohn's disease landscape & forecast p.g. 39, Published Sep 2022

ⁱⁱ Chan et al, 2018