

## REDX PHARMA LIMITED

("Redx" or the "Company")

### Redx's RXC008 Granted US FDA Fast Track Designation for Fibrostenotic Crohn's Disease

**Alderley Park, UK, 10 March 2026** [Redx Pharma Ltd](#), the clinical-stage, biotechnology company focused on developing novel, small molecule, targeted medicines for fibrotic disease announces that the US Food and Drug Administration (FDA) has granted Fast Track Designation to RXC008, a GI-Restricted pan-ROCK inhibitor being developed as a potential first-in-class treatment for fibrostenotic Crohn's disease.

**Lisa Anson, CEO, Redx Pharma commented:** "We are delighted to have received Fast Track designation for RXC008. Currently there is no therapeutic treatment for fibrostenotic Crohn's disease leaving many patients with invasive, repetitive surgical interventions as their only option. These surgeries can have a significant impact on the physical and emotional wellbeing of these patients, with many suffering complications such as short-bowel syndrome or ultimately resulting in the use of a stoma. From our preclinical studies RXC008 has shown the potential to halt or reverse the formation of fibrosis in the GI-tract which would revolutionise the treatment of this aspect of the disease. Redx have been working closely with the FDA and the STAR consortium to define the regulatory pathway for this disease and following our positive pre-clinical and Phase 1 data, we look forward to commencing our Phase 2 study later this year."

#### 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. RXC008 has completed a Phase 1 study which showed good tolerability and tissue exposure with no clinically relevant breakthrough or hypotension observed, and a good safety profile with no serious adverse events.

#### About Fast Track Designation<sup>1</sup>

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. A drug that receives Fast Track designation may benefit from things such as: more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers; eligibility for Accelerated Approval

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<sup>1</sup> <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

and Priority Review, if relevant criteria are met and; rolling review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

### **About Crohn's disease**

Crohn's disease affects 1.7m<sup>2</sup> people globally and >70,000 new cases are diagnosed each year. More than 50% of patients<sup>3</sup> 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 is a clinical-stage biotechnology company focused on the development of novel, small molecule, targeted medicine for the treatment of fibrotic disease. Pioneering the next generation of anti-fibrotic medicines, the Company is currently progressing RXC008, a first-in-class GI-restricted pan-ROCK inhibitor for the treatment of fibrostenotic

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<sup>2</sup> Clarivate, Crohn's disease landscape & forecast p.g. 39, Published Sep 2022

<sup>3</sup> Chan et al, 2018

Crohn's disease through the clinic and has completed a Phase 2a program in idiopathic pulmonary fibrosis (IPF) with zelasudil, a potential best-in-class selective ROCK2 inhibitor.

Additionally, the Company has an early-stage discoidin domain receptor (DDR) inhibitor program with potential to be a first-in-class approach for chronic kidney disease. 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 assets and discovery pipeline, but also by its strategic transactions including with AstraZeneca and Jazz Pharmaceuticals, as well as the sale of pirtobrutinib (RXC005, LOXO-305) to Loxo Oncology (Eli Lilly). Pirtobrutinib, the only approved non-covalent or reversible Bruton's tyrosine kinase (BTK) inhibitor, has transitioned quickly from FDA approval in the US, to broader international approvals.