

REDX PHARMA PLC
("Redx" or the "Company")

Redx Announces First Patient Dosed in Phase 2 Clinical Trial of RXC004 in Patients with Advanced Colorectal Cancer

First wholly-owned Redx asset to enter Phase 2 clinical trial

Study will assess efficacy and safety of RXC004 in patients with Wnt-ligand driven metastatic colorectal cancer

Alderley Park, UK, 15 November 2021 - Redx Pharma (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, today announces that the first patient has been dosed in the monotherapy arm of the Phase 2 clinical trial of its investigational drug RXC004 in patients with advanced microsatellite stable (MSS) metastatic colorectal cancer (mCRC) who have progressed following treatment with standard of care. RXC004 is Redx's wholly-owned, highly potent and selective, orally active once-daily Porcupine inhibitor being developed as a targeted therapy for Wnt-ligand driven cancer.

The multi-centre Phase 2 clinical trial ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04907539) NCT04907539) will evaluate preliminary efficacy and safety of RXC004 in genetically-selected patients with Ring finger protein 43 (RNF43) or R-spondin (RSPO) aberrated, advanced MSS mCRC. Topline data is expected to report in the first half of 2023.

A second arm of the trial, evaluating RXC004 in combination with the anti-PD-1 antibody nivolumab in patients with MSS mCRC, is expected to commence in the first half of 2022 once a recommended dose has been established in the ongoing Phase 1 dose escalation combination trial.

Dr Natalie Cook, University of Manchester and Christie NHS Foundation Trust, UK, and International Coordinating Investigator of the study in the UK, commented: *"Microsatellite stable metastatic colorectal cancer is a devastating disease, with limited treatment options. A subgroup of these colorectal cancers possess RNF43 mutations or RSPO fusions leading to activation of the Wnt pathway as a driver of the cancer. This study will assess whether RXC004, a novel Porcupine inhibitor, has a clinically meaningful anti-cancer effect in this well-defined patient cohort."*

Lisa Anson, Chief Executive Officer of Redx Pharma, added: *"We are excited to be dosing patients in Redx's first ever Phase 2 clinical trial of a wholly-owned drug candidate, an important corporate milestone. Our encouraging Phase 1 results, recently reported at the ESMO Congress, combined with our preclinical data, strongly support the hypothesis that patients with Wnt-ligand driven tumours could benefit from RXC004."*

A second Phase 2 clinical trial evaluating RXC004 as a monotherapy in advanced genetically selected pancreatic cancer and unselected biliary cancer is also expected to start in 2021.

For further information, please contact:

Redx Pharma Plc T: +44 (0)1625 469 918

UK Headquarters
Lisa Anson, Chief Executive Officer
Karl Hård, Head of Investor Relations
k.hard@redxpharma.com

US Office
Peter Collum, Chief Financial Officer

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/ 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 microsatellite stable metastatic colorectal cancer (MSS mCRC)

Metastatic colorectal cancers have a poor prognosis with a 5-year survival rate of approximately 15% (1). Standard first line and second line treatments are combinations of chemotherapy and a VEGF inhibitor or EGFR inhibitor. MSS cancers account for 95% of metastatic CRC and tend to be unresponsive to treatment with immune checkpoint inhibitors. In the third line treatment setting the response rate to standard agents is <5%, median progression free survival is approximately 2 months and overall survival approximately 6 months (2,3). Approximately 8% of MSS mCRC patients have Wnt-ligand driven tumours (3% RNF43 mutations and 5% RSPO fusions) (4).

(1) <https://seer.cancer.gov/statfacts/html/colorect.html>

(2) Grothey A et al. Lancet 2013; 381(9863):303-12

(3) Mayer RJ, et al. N. Engl. J. Med. 2015; 372:1909-19

(4) <https://www.cbiportal.org>

About RXC004

RXC004 is a wholly owned, potent, selective, oral, small-molecule inhibitor of the Porcupine enzyme, a key activator of Wnt ligands in the Wnt-signalling pathway. The Wnt pathway is well established as a driver of both tumour growth and immune evasion. Aberrant Wnt signalling contributes directly to tumour growth and plays an important role in immune evasion, which has also been linked to resistance to immune-checkpoint inhibitors (ICIs) such as nivolumab. By selecting patients with tumours that have high Wnt-ligand dependency, such as those with loss of function mutations in the RNF43 gene and fusions in the RSO gene family, RXC004 has an opportunity to both directly inhibit the tumour growth and have an immune-enhancing effect to allow the patient's immune system to better recognise and attack the tumour.

ICIs such as anti-PD-1 antibodies have revolutionised the treatment of cancer, but do not work in all patients. Wnt-pathway activation can enhance the ability of the tumour to evade destruction by the immune system and has been linked to lack of response to ICIs in these tumours. Redx scientists have observed in preclinical studies that RXC004 can block activation of the Wnt pathway and restore the ability of the immune system to fight the tumour. Thus, RXC004 offers potential to address some of the shortcomings of ICI therapies through increasing both response rates and duration of response, particularly in patient populations unresponsive to ICI therapy.

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, aiming initially to progress them to clinical proof of concept before evaluating options for further development and potential value creation. Redx's lead oncology product candidate, the Porcupine inhibitor RXC004, commenced a Phase 2 programme in November 2021. The Company's selective ROCK2 inhibitor product candidate, RXC007, is in development for idiopathic pulmonary fibrosis and commenced a Phase 1 clinical trial in June 2021. Initial results were reported in October 2021, with full Phase 1 results expected in 2022.

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 the two wholly-owned clinical-stage product candidates and rapidly expanding pipeline, but also by the four strategic transactions from which has emerged the most advanced product candidate pirtobrutinib (RXC005, LOXO-305), a BTK inhibitor now in Phase 3 clinical development by Eli Lilly following its acquisition of Loxo Oncology. In addition, Redx has forged pre-clinical collaborations with AstraZeneca and Jazz Pharmaceuticals.

Forward-Looking Statements

This press release contains forward-looking statements about our business. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the clinical development of RXC004, including in respect of data to be reported therefrom and potential benefits thereof to patients if approved. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements, including suspensions, delays or other developments in the Company's clinical trials and regulatory developments. All information in this press release is as of the date of the release, and the company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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