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Redx Pharma plc
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REDX PHARMA PLC

("Redx" or "the Company")

Redx Announces RXC004 Topline Data From a Phase 2 Monotherapy Module

Overall efficacy results not sufficient to support further development as a monotherapy in advanced biliary tract cancer patients.

Primary RXC004 efficacy hypothesis is to overcome immune evasion and enhance the anti-tumour activity of immune checkpoint inhibitors; *top-line data from combination treatment modules expected in H2 2023.*

Alderley Park, UK, 8 March 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 topline monotherapy data from the biliary tract cancer (BTC) module of the RXC004 PORCUPINE2 Phase 2 clinical trial programme.

RXC004 is an orally active, once daily, porcupine inhibitor being developed as a targeted treatment for Wnt-ligand dependent cancers. The objective of the Phase 2 programme is to provide an initial assessment of the efficacy and safety of the drug both as a single agent and in combination with anti-PD-1 therapy, in patients with certain Wnt-ligand dependent solid tumours whose cancers have progressed following standard of care therapies. The RXC004 Phase 2 clinical development programme consists of two studies, PORCUPINE and PORCUPINE2, which are detailed below.

The data announced today, the first from the Phase 2 programme, are from 16 previously treated patients enrolled in the advanced BTC monotherapy arm of the PORCUPINE2 study. The primary endpoint was Progression Free Survival at six months. Some patients received durable clinical benefit from RXC004 in this cohort, consistent with clinical activity seen in the Phase 1 trial, and the safety profile of RXC004 in this module was also consistent with the safety data previously reported in the Phase 1 trial. However, the overall results are not sufficient to support the further development of RXC004 as a monotherapy in this treatment setting.

Planned retrospective analysis of all efficacy and biomarker data in this BTC monotherapy cohort will increase the understanding of the single agent activity of RXC004 and will be used to aid interpretation of the ongoing combination module efficacy, where RXC004 is used alongside anti-PD-1 therapy, pembrolizumab.

"Our Phase 2 program is designed to explore the activity of RXC004 both as monotherapy and in combination with immune checkpoint inhibitors, consistent with its postulated dual mechanism of action. Our primary efficacy hypothesis is that in combination it can overcome immune evasion and anti-PD-1 resistance, which could open new patient segments," **said Dr Jane Robertson, Chief Medical Officer, Redx Pharma.** *"While today's results do not support further clinical development of RXC004 as monotherapy in recurrent BTC, where very few drugs have received regulatory approval as single agents in this hard-to-treat disease, they are nonetheless consistent with the overall hypothesis that RXC004 has potential as an active component of combination therapy. We look forward to the data read out from the combination module with pembrolizumab, that is expected in the second half of this year."*

Biliary tract cancer, a cancer with an annual incidence of 51,000 patients[1], has an extremely poor prognosis, with only a 2% 5-year survival rate[2] and a treatment response rate of less than 5% with standard second-line chemotherapy.

About the RXC004 Phase 2 Clinical Trial Program

The first study in the Phase 2 programme, PORCUPINE, (clinicaltrials.gov NCT04907539) is focused on patients with advanced microsatellite stable metastatic colorectal cancer (MSS mCRC) that has not progressed following treatment with standard of care and is evaluating preliminary efficacy and safety of RXC004 in genetically selected patients with Ring finger protein 43 (RNF43) or R-spondin (RSPO) aberrated, advanced MSS mCRC. A second Phase 2 study of RXC004, PORCUPINE2, (clinicaltrials.gov NCT04907851), for genetically selected pancreatic cancer and biliary cancer, a highly Wnt-ligand dependent cancer is also ongoing.

Given the dual mechanism of action of RXC004, which preclinically was shown to inhibit tumour growth and immune evasion, there is a strong rationale for immune therapy combination. In November 2022, Phase 1 clinical data evaluating the safety and tolerability of RXC004 in combination with nivolumab, in patients with advanced malignancies was presented as a poster at the Society of Immunotherapy of Cancer (SITC) Conference. The data was suggestive of an anti-tumour immune response, which is reported to correlate with an improved response to anti-PD-1 immune checkpoint inhibitors. The results of the study supported a dose selection of 1.5mg once daily to be used in combination modules of both PORCUPINE and PORCUPINE2.

The combination module of the PORCUPINE trial will evaluate RXC004 in combination with nivolumab, (OPDIVO® - Bristol Myers Squibb, a PD-1 inhibitor) in MSS mCRC and this module is now open for recruitment in all countries taking part in the trial including the US and the UK. The combination module of the PORCUPINE2 study, (clinicaltrials.gov NCT04907851), will evaluate RXC004 in combination with pembrolizumab, (KEYTRUDA® - MSD's anti-PD-1 therapy) in biliary tract cancer. A clinical trial supply and collaboration agreement was entered into with MSD (Merck & Co., Inc., Rahway, NJ, USA) in December 2022 for the supply of KEYTRUDA®, and this module is open for recruitment in all countries taking part in this clinical trial including the UK and Australia.

The person responsible for the release of this announcement on behalf of the Company is Claire Solk, Company Secretary.

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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, with topline data expected in Q1 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 both monotherapy and combination with anti-PD-1 Phase 2 data during 2023. 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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[1] Incidence data sourced from GlobalData Epidemiology data (Major Markets: US, EU5, Japan, China)
[2] www.cancer.net

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