

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

**Redx Pharma Announces Phase 2 Dose Selection of its Porcupine Inhibitor, RXC004**

*Monotherapy Phase 2 Proof of Concept programme will evaluate RXC004 in selected patients with three cancer types having high Wnt-ligand dependency, with planned start H2 2021*

*Data from RXC004 monotherapy Phase 1 trial to be presented at ESMO*

**Alderley Park, 27 July 2021** Redx Pharma (AIM: REDX), the drug discovery and development company focused on cancer and fibrosis, announces it has selected 2 mg once daily as the dose of RXC004 for the planned Phase 2 monotherapy, proof of concept clinical trials based on the safety profile observed in Phase 1. The studies are expected to start during the second half of 2021. RXC004 is the Company's lead drug candidate and is a highly potent, orally active porcupine inhibitor being developed as a targeted therapy for Wnt-ligand driven cancer. Porcupine is a key enzyme in the Wnt pathway, well established as a key driver of both tumour growth and immune evasion.

The selection of a dose and decision to move RXC004 into Phase 2, follows the successful recruitment of all patients to the monotherapy arm of the Company's ongoing open label dose escalation Phase 1 study (NCT03447470). The primary objective of the Phase 1 study was to establish the safety and tolerability of RXC004 in patients. Preliminary data from the study in patients with unselected advanced solid tumours, showed that RXC004 2mg once daily was safe, tolerated and provided target coverage at levels required to assess monotherapy efficacy in Phase 2 clinical trials in selected patients with Wnt-ligand driven cancers. Whilst the Phase 1 study was in genetically unselected cancers, the data suggested a differential level of activity between Wnt-ligand driven cancers and non Wnt-ligand driven cancers, in line with observations of other molecules in this class. Redx plans to present the monotherapy results from the Phase 1 study at the ESMO Congress in September 2021.

**Lisa Anson, Chief Executive Officer of Redx Pharma commented** *"Our Phase 1 monotherapy study supports our belief that RXC004 has the potential to be a significant, novel targeted medicine for the treatment of Wnt-ligand driven cancer. Our distinctive approach to drug discovery has enabled our highly talented scientific team to design our Porcupine Inhibitor to unlock the therapeutic potential of Wnt pathway blockade, a long sought-after oncology target. The decision to progress to Phase 2 and the selection of our monotherapy dose represent major milestones in the clinical development of our lead asset."*

**Jane Robertson, Chief Medical Officer of Redx Pharma added** *"The Redx team and our investigators are excited to move forward into Phase 2 clinical studies to evaluate the efficacy of RXC004 as monotherapy in selected patients with mCRC, pancreatic and biliary tract cancers, whose tumours have high Wnt-ligand dependency. We look forward to initiating these studies in the coming months."*

**About the Phase 2 programme**

Redx plans to commence a global Phase 2 monotherapy programme in three tumour types to assess RXC004 efficacy in patients with Wnt ligand-driven cancers. In two tumour types, microsatellite stable metastatic colorectal cancer (MSS mCRC) and pancreatic cancer, the studies will enrol only patients whose tumours have high Wnt-ligand dependency resulting from specific genetic aberrations (RNF43 mutations and/or RSPO fusions). A third proof of concept study will enrol patients diagnosed with biliary tract cancer, a tumour known to have high Wnt-ligand dependency. All three of these cancer types have high unmet need with limited treatment options and poor 5-year survival rates of less than 3% for biliary and pancreatic cancer and 14% for mCRC. All three studies are planned to commence in H2 2021 and initial results could be available from 2022.

RXC004 is also currently being investigated in a Phase 1 study in combination with nivolumab (OPDIVO® - Bristol Myers Squibb, an anti-PD-1 antibody). The primary objective of this arm of the study is to evaluate the safety and tolerability of this combination in patients with unselected advanced malignancies. The results from this combination study are expected in H2 2021 and will be used to define a dose of RXC004 to be used in combination with standard dose nivolumab in a Phase 2 study in patients with genetically selected microsatellite stable (MSS) metastatic colorectal cancer (MSS mCRC).

**For further information, please contact:**

**Redx Pharma Plc**  
**UK Headquarters** Lisa Anson, Chief Executive  
**US Office** Peter Collum, Chief Financial Officer  
**T: +44 1625 469 918**

**SPARK Advisory Partners (Nominated Adviser)**  
**T: +44 203 368 3550**

Matt Davis/Adam Dawes

**WG Partners LLP (Joint Broker)**  
**T: +44 20 3705 9330**

Claes Spång/Nigel Birks/David Wilson

**Panmure Gordon (UK) Limited (Joint Broker)**  
**T: +44 20 7886 2500**

Rupert Dearden/Freddy Crossley/Emma Earl

**FTI Consulting**  
**T: +44 20 3727 1000**

Simon Conway/Ciara Martin

**About RXC004**

RXC004 is a potent, selective, oral, small molecule inhibitor of the enzyme, porcupine, 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 such as nivolumab. By selecting patients with tumours that have high Wnt-ligand dependency, such as tumours with mutations in the RNF43 gene and fusions in the RSPO 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.

Immune checkpoint inhibitors (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. Our scientists have demonstrated preclinically 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 as a monotherapy or combination therapy.

### **About Redx Pharma Plc**

Redx Pharma (AIM:REDX) is focused on the discovery and development of novel targeted medicines for the treatment of cancer and fibrotic diseases, aiming initially to progress them to clinical proof of concept, before evaluating options for further development and potential value creation. Redx's lead oncology asset, RXC004 is expected to commence a Phase 2 programme in H2 2021. The Company's selective ROCK2 inhibitor, RXC007, is in development for idiopathic pulmonary fibrosis and commenced a Phase 1 clinical study in June 2021 for which results are expected in 2022.

The Company has a strong track record of discovering new drug candidates through its core capability of converting medicinal chemistry insights into differentiated and commercially attractive drug candidates with five Redx assets in late pre-clinical or clinical development. One of those assets, a BTK inhibitor - pirtobrutinib/LOXO 305, was sold to Loxo Oncology (now Eli Lilly) and is currently in Phase 3 clinical studies in chronic lymphocytic leukaemia. Redx has forged pre-clinical asset partnerships with blue chip companies including AstraZeneca and Jazz Pharmaceuticals.

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