Redx to resume RXC004 clinical trial programme

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REDX PHARMA PLC

("Redx" or "the Company")

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MHRA grants approval for trial restart

Phase 1/2a trial on track to resume in H1 2019

Alderley Park, 21 January 2019 Redx (AIM: REDX), the drug discovery and development company focused on cancer and fibrosis, announces that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has given formal approval to the Company to re-commence the phase 1/2a trial for RXC004, an oral porcupine inhibitor targeting the Wnt signalling pathway. Clinical evaluation of RXC004 in patients with advanced solid tumours remains on track to resume in H1 2019 following the approval of a revised phase 1/2a clinical trial protocol and drug formulation. Redx, together with the study investigators, now believe that the desired systemic exposure can be achieved using a significantly lower starting dose with the potential for clinical benefit[1].

Natalie Cook, Consultant Oncologist and Principal Investigator from the Christie Hospital in Manchester, UK commented: "We have learnt a significant amount from the first patient treated with RXC004, and this provides the basis for an optimised RXC004 development plan as well as the confidence to evaluate the clinical potential of RXC004 in cancer patients."

Lisa Anson, Chief Executive Officer, Redx Pharma plc commented: “I am delighted that Redx is on track to resume clinical evaluation of RXC004 in patients with advanced solid tumours in the first half of 2019. We believe that the revised RXC004 clinical protocol and development plan has the potential to offer clinical benefit both as a monotherapy and in combination with standard of care treatments. We look forward to working closely with our expert clinical oncology colleagues across the U.K. on this exciting programme.”

On successful completion of this initial phase 1 monotherapy study, RXC004 has the potential to be developed in different cancers and in different treatment settings with major unmet medical need based on two distinct mechanisms of actions: as an immuno-oncology agent and by direct tumour targeting in patients with upstream Wnt signalling pathway alterations.

[1] The primary objective of the study remains the safety and tolerability of the drug

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About Redx Pharma Plc

Redx is a UK based biotechnology company whose shares are traded on AIM (AIM:REDX). Redx's vision is to become a leading biotech focused on the development of novel precision medicines that have the potential to transform treatment in oncology and fibrotic diseases.

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About RXC004 and the Clinical Programme

RXC004 is a novel, oral, potent small molecule Porcupine inhibitor, which targets the Wnt signalling pathway. Porcupine is a recognised drug target on the Wnt cell signaling pathway. The Wnt signalling pathway is an embryonic signalling pathway that is implicated in the maintenance of cancer stem cells in multiple cancer types. This pathway is associated with tumorigenesis, metastasis, recurrence and resistance in cancer. There is now also strong evidence that this pathway plays a key role in how tumours avoid detection by the patient's own tumour fighting immune cells, tumours of this type have been termed "cold" tumours.

The first-in-man clinical trial for this drug is a modular, multi-arm, multi-part, Phase 1/2a, adaptive design study whose primary objective is to evaluate the safety and tolerability of the drug in patients with advanced malignancies. It is anticipated that a total c.50 patients will be enrolled. (ClinicalTrials.gov Identifier: NCT03447470). In the first part of the study patients are allocated to a dose and followed for a period of time for potential dose limiting toxicities. Under the proposed amended protocol patient dosing will be recommenced at 0.5mg as opposed to the original starting dose of 10mg. Dose-escalation will then occur stepwise in subsequent groups of patients until a maximum tolerated dose or evidence of anti-tumour effects are observed.

As previously announced, following treatment of the first patient, Redx suspended recruitment to its phase 1/2a clinical study for RXC004 in March 2018. This was due to the observation of clinically significant adverse events, which were believed to be related to the on-target effects of RXC004 on the inhibition of the Wnt signalling pathway. Further analysis of clinical data from this first patient indicated that the systemic RXC004 exposure was significantly higher than that predicted from pre-clinical animal studies. While the maximum plasma concentration of the drug (C_{max}) was in line with expectations, the terminal half-life of the drug ($t_{1/2}$) was significantly longer than that predicted from such animal models, due to the actual rate of elimination being lower. The Company believes that higher drug exposure in humans compared to pre-clinical studies is not uncommon in first in human clinical studies of experimental drugs. It arises from differences between the metabolism observed in the animals used in pre-clinical models versus that observed when administered to humans for the first time.