First Cohort of Patients Successfully Dosed in RXC004 Phase 1/2 Study; Second Cohort Enrolment Has Now Begun

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Alderley Park, 19 August 2019 Redx (AIM: REDX), the drug discovery and development company focused on cancer and fibrosis, announces that it has successfully completed dosing of the first cohort of patients in its ongoing phase 1/2 study with RXC004. Following a review of the data from this cohort, the Safety Review Committee has recommended that the dose can now be escalated. Consequently, recruitment of the second patient cohort, who will be administered the drug at a higher pre-specified dose of RXC004, has begun as per the trial protocol.

RXC004 is an oral porcupine inhibitor targeting the Wnt signalling pathway. 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. The Phase 1 monotherapy dose-escalation study is expected to complete in H1 2020 along with start of monotherapy dose-expansion.

Lisa Anson, Chief Executive Officer of Redx Pharma added: “We are pleased that the Safety Review Committee has recommended that we can now escalate the dose in the phase 1 /2 study of RXC004, our oral porcupine inhibitor, and consequently we have begun enrolment of our second cohort of patients as per protocol. We believe that RXC004 has the potential to offer clinical benefit both as a monotherapy and in combination with standard of care treatments for patients with Wnt-driven advanced solid tumours. We look forward to completing patient enrolment for the phase 1 monotherapy dose-escalation study and to announcing results during 2020.”

Background on 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 signaling pathway which 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; often termed as "cold" tumours.

The first-in-man clinical trial for RXC004 is a modular, multi-arm, multi-part, Phase 1/2, 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 of 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 protocol, patient dosing of the first cohort was at 0.5mg and 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 1/2 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. Following discussions with the Company, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) approved a revised phase 1/2 clinical trial protocol and drug formulation in January 2019, allowing re-commencement of the RXC004 study.

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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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