

RXC004 Clinical Trial Update

29 Mar 2018

Alderley Park, March 29 2018 – Redx (AIM: REDX), the drug discovery and development company focused on cancer and fibrosis, announces that it has informed the Medicines and Healthcare products Regulatory Agency (MHRA, "the Agency") that it is temporarily interrupting patient accrual to its Phase 1/2a clinical study for the Porcupine inhibitor, RXC004.

On dosing of the first patient in the trial, clinically significant adverse events were observed that the company and our academic colleagues believe are possibly related to RXC004 on-target effects and Wnt pathway inhibition. Importantly, analysis of data from this first patient indicates that their systemic RXC004 exposure was significantly higher than that predicted from preclinical studies.

Dr Andrew Saunders, Chief Medical Officer of Redx Pharma commented: "It is our current intention to propose a protocol amendment that enables dose-escalation to re-start at significantly lower dose levels. This protocol amendment will be finalised with consultation with both the MHRA and principal investigators."

lain Ross Executive Chairman added: "The Board continues to believe the overall risk/benefit assessment of RXC004 as an investigational drug is unchanged. However, in drug development, safety of patients is the first priority and it is appropriate that the Board and management has taken the decision to suspend recruitment of further patients to the trial until the Company has consulted with the MHRA and agreed a plan to move forward. While we remain confident that we can address this issue, we currently estimate that this suspension will lead to a delay of several months. The Board continues to believe it has sufficient resources to continue to progress RXC004 and its broader portfolio of oncology and fibrosis assets. We intend to provide a further update in due course."

Background

RXC004 is a novel, oral, potent small molecule Porcupine inhibitor, which targets the Wnt pathway, 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.

This first-in-man clinical trial of RXC004 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 time for potential dose limiting toxicities. Once this period is complete the protocol dictates that the next arm of the study will be at a higher dose until a maximum tolerated dose is reached.

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About Redx Pharma Plc

Redx is a UK biotechnology company whose shares are traded on AIM (AIM:REDX). Redx is focused on creating and developing first, or potentially best in class drugs, in specific areas of cancer and fibrosis that address significant unmet medical need. Redx has an in-house discovery team with proven world-class chemistry capabilities.