RNS Number : 5866U
Redx Pharma plc
06 December 2021

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

Redx and Caris Life Sciences Announce Strategic Partnership to Accelerate Phase 2 Study Recruitment in the U.S.

RXC004 Phase 2 IND is open for patients with genetically-defined Wnt-ligand dependent colorectal cancer

Redx will leverage Caris' precision development programme including comprehensive molecular profiling, trial matching and real-world data

Alderley Park, United Kingdom and Irving, Texas, 6 December 2021 - Redx Pharma (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, and Caris Life Sciences® ("Caris"), the leading molecular science and technology company actively developing and delivering innovative solutions to revolutionize healthcare, today announce that they have entered into a strategic partnership. The partnership will leverage Caris' comprehensive Whole Transcriptome Sequencing (WTS) and Whole Exome Sequencing (WES) platform assay, real-world data and its Right-In-Time™ (RIT) clinical trial solutions to enhance the speed of U.S. accruals for Redx's Phase 2 trial for the investigational Porcupine inhibitor, RXC004, in genetically-selected patients with Wnt-ligand dependent microsatellite stable (MSS) metastatic colorectal cancer (mCRC).

Utilizing Caris' RIT clinical trial solution will help Redx match the right U.S. patients to the Phase 2 trial based on both the individual patient's molecular tumour profile and the trial's eligibility requirements, i.e., those whose cancers carry Ring Finger Protein 43 (RNF43) loss of function mutations or R-spondin (RSPO) fusions with MSS mCRC, and have progressed following therapy with current standard of care. Through the nationwide identification of eligible patients with the required genetic characteristics Caris' flexible enrolment model will enable rapid initiation of study treatment for RXC004 at its extensive network of U.S. RIT trial sites, in addition to trial sites initiated by Redx.

Lisa Anson, Chief Executive Officer of Redx Pharma, said: *"We are delighted to be partnering with Caris on several of their innovative technologies and approaches. Together we aim to greatly enhance the speed of our patient accrual for the U.S. into PORCUPINE, our RXC004 Phase 2 trial in patients with Wnt-ligand driven metastatic colorectal cancer who currently have few treatment options. The Caris approach will complement our screening capabilities, and potentially identify new populations where RXC004 may have utility."*

"*Unlike more limited panels, Caris tests all 22,000 genes in both DNA and RNA, which minimizes the potential of missing alterations that would inform drug development decisions,*" **said Brian Lamon Ph.D., Chief Business Officer, Head of BioPharma Business Development at Caris Life Sciences.** "*We will comprehensively deploy all of our precision oncology tools to support and maximize the success of the RXC004 program.*"

The RXC004 Phase 2 trial in MSS mCRC patients (NCT04907539), known as the PORCUPINE trial, prospectively selects patients with Wnt-ligand dependence for treatment with Redx's Porcupine inhibitor, RXC004. The study will recruit patients from the U.K., U.S., Spain and South Korea. The prevalence of the upstream Wnt pathway aberrations which drive Wnt-ligand dependence in MSS mCRC, RNF43 loss of function mutations and RSPO-fusions, is around 8%. As such, identification of potentially eligible MSS mCRC patients involves a significant screening effort. The International Coordinating Investigator in the U.S. for PORCUPINE, the RXC004 Phase 2 trial in colorectal cancer, is Professor Scott Kopetz at The University of Texas MD Anderson Cancer Center, Houston, TX.

The strategic partnership between Redx and Caris will also include a real-world evidence collaboration, using Caris' extensive database of genetic aberrations, therapeutic interventions and patient outcomes, to understand the clinical outcomes for MSS CRC patients with these genetic aberrations. Utilizing Caris' comprehensive data set will allow Redx to further characterize the target patient population, and potentially identify additional patient populations in MSS CRC where RXC004 may have efficacy.

Financial terms have not been disclosed.

For further information, please contact:

Redx Pharma Plc T: +44 (0) 1625 469 918

UK Headquarters
Lisa Anson, Chief Executive Officer
Karl Hård, Head of Investor Relations
k.hard@redxpharma.com

US Office
Peter Collum, Chief Financial Officer

SPARK Advisory Partners (Nominated Adviser) T: +44 (0)203 368 3550

Matt Davis/ Adam Dawes

WG Partners LLP (Joint Broker) T: +44 (0)203 705 9330

Claes Spång/ David Wilson

Panmure Gordon (UK) Limited (Joint Broker) T: +44 (0)207 886 2500

Rupert Dearden/ Freddy Crossley/ Emma Earl

FTI Consulting T: +44 (0)203 727 1000

Simon Conway/ Ciara Martin

Caris Corporate Contact:
Brian Lamon, Chief Business Officer
Caris Life Sciences
blamon@carisls.com

Caris Life Sciences Media Contact:
Allison Kreutzjans
Edelman
Caris@Edelman.com
+1 (314) 550-1327

About RXC004
RXC004 is a wholly owned, potent, selective, oral, small-molecule inhibitor of the Porcupine enzyme, 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 (ICIs) such as nivolumab. By selecting patients with tumours that have high Wnt-ligand dependency, such as those with loss of function 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.

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. Redx scientists have observed in preclinical studies 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 to address some of the shortcomings of ICI therapies through increasing both response rates and duration of response, particularly in patient populations unresponsive to ICI therapy.

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, aiming initially to progress them to clinical proof of concept before evaluating options for further development and potential value creation. Redx's lead oncology product candidate, the Porcupine inhibitor RXC004, commenced a Phase 2 programme in November 2021. The Company's selective ROCK2 inhibitor product candidate, RXC007, is in development for idiopathic pulmonary fibrosis and commenced a Phase 1 clinical trial in June 2021. Initial results were reported in October 2021, with full Phase 1 results expected in 2022.

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 the two wholly-owned clinical-stage product candidates and rapidly expanding pipeline, but also by the four strategic transactions from which has emerged the most advanced product candidate pirtobrutinib (RXC005, LOXO-305), a BTK inhibitor now in Phase 3 clinical development by Eli Lilly following its acquisition of Loxo Oncology. In addition, Redx has forged pre-clinical collaborations with AstraZeneca and Jazz Pharmaceuticals.

Forward-Looking Statements
This press release contains forward-looking statements about our business. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the clinical development of RXC004, including in respect of data to be reported therefrom and potential benefits thereof to patients if approved. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements, including suspensions, delays or other developments in the Company's clinical trials and regulatory developments. All information in this press release is as of the date of the release, and the company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

About Caris Life Sciences
Caris Life Sciences® (Caris) is the leading molecular science and technology company actively developing and delivering innovative solutions to revolutionize healthcare and improve patient outcomes. Through comprehensive molecular profiling (Whole Exome and Whole Transcriptome Sequencing) and the application of advanced artificial intelligence (AI) and machine learning algorithms, Caris has created the large-scale clinico-genomic database and cognitive computing needed to analyze and unravel the molecular complexity of disease. This information provides an unmatched resource and the ideal path forward to conduct the basic, fundamental research to accelerate discovery for detection, diagnosis, monitoring, therapy selection and drug development to improve the human condition.
With a primary focus on cancer, Caris' suite of market-leading molecular profiling offerings assesses DNA, RNA and proteins to reveal a molecular blueprint that helps patients, physicians and researchers better detect, diagnose and treat patients. Caris' latest advancement, which is currently available within its Precision Oncology Alliance, is a blood-based, circulating nucleic acids sequencing (cNAS) assay that combines comprehensive molecular analysis (Whole Exome and Whole Transcriptome Sequencing from blood) and serial monitoring - making it the most powerful liquid biopsy assay ever developed.

Headquartered in Irving, Texas, Caris has offices in Phoenix, New York, Denver and Basel, Switzerland. Caris provides services throughout the U.S., Europe, Asia and other international markets. To learn more, please visit CarisLifeSciences.com or follow us on Twitter (@CarisLS).

END

MSCFLFVDFVLVIIL