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ValiRx PLC
20 June 2019

VALIRX PLC

("ValiRx" or the "Company")

CLINICAL UPDATE

MHRA and REC approve a major update to the trial of VAL201 including the appointment of a Principle Investigator to the clinical team

Results from the first clinical trial of VAL201 are being prepared for an independent evaluation following the completion of the current patient group.

London, UK, *20 June 2019*: ValiRx Plc (AIM: VAL), the clinical stage biotechnology company, provides an update on its therapeutic drugs, VAL201 and its current clinical status.

VAL201 clinical trial

ValiRx is pleased to announce that based on its clinical results, a substantial amendment to the clinical trial protocol has received regulatory approval from the Medicines and Healthcare products Regulatory Agency ("MHRA") and the Research ethics committee (REC)

Following approval of the substantial amendment, an authoritative prostate cancer specialist, Dr Mark Linch has been appointed as Principal Investigator to the clinical trial team at University College London Hospital ("UCLH"). Dr Linch is an Honorary Senior Lecturer at University College London (UCL) Cancer Institute, where he leads the Uro-oncology Biology Group, and he is also a Consultant Medical Oncologist specialising in the treatment of prostate and bladder cancer at UCLH. Dr Rebecca Kristeleit continues with the study as Chief Investigator.

To date, the results generated by the trial, aided by sizable analytical methods developments, have shown that safe toxicological limits can be significantly elevated and applied to much higher levels in humans, than was suggested by the pre-clinical studies. The approval given to relax the restrictions previously applied to the trial, mean that a more effective use of VAL201 can be achieved, with respect to concentration and timing and regarding increased flexibility in the administration of the drug.

Additionally, the amendment relating to dosing strategies means that, in light of accumulated clinical data, the Company is able to develop further protocols. These will be designed to evaluate a range of defined therapeutic approaches that are to be tested against each other,

to determine the most effective approach, in terms of disease management, cost effectiveness and patient welfare, in further clinical trials. These protocols will be the precursor to seeking approval to conduct trials aimed at gaining sufficient data to secure partnering and then Market Approval Application.

ValiRx reports that the trial thus far has met all the primary and secondary endpoints. The safety and tolerability results continue to be acceptable and further evidence of the compound's positive effect in reducing the progress of prostate cancer has been witnessed. The data from the trial is currently being collated for examination by independent third party experts. The approval of the amendment further validates the Company's clinical development throughout VAL201's First-in-Human Trial. Further information connected to the data and the results and findings from the trial will form the basis of a report outlining the compound's clinical profile and behaviour, which will be published in due course.

Dr George Morris, COO of ValiRx, commented:
"This substantial amendment has taken a lot of effort from the whole team both internal and by all our service providers to achieve. I am profoundly grateful to them all. The most gratifying thing is that our original pre-clinical experimental data has held up well and been vindicated throughout the whole of this first-in-human trial. Now, as the trial is delivering an extensive and positive output, it is also providing practical information back to the trialling of VAL201, so that the next stage of clinical development, in which we will endeavour to show how effective the compound actually is, can be entered into with confidence and support from all those involved."

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.

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For more information, please contact:

ValiRx plc	**Tel: +44 (0) 20 3008 4416**
	www.valirx.com
Dr Satu Vainikka, Chief Executive	**Tel: +44 (0) 20 3008 4416**
Tarquin Edwards, Head of Communications.	**Tel: +44 (0) 7879 458 364**
	tarquin.edwards@valirx.com
Cairn Financial Advisers LLP (Nominated Adviser)	**Tel: +44 (0) 20 7213 0880**
Liam Murray/Jo Turner/Ludovico Lazzaretti	
Novum Securities Limited (Broker)	**Tel: +44 (0) 20 7399 9400**
Colin Rowbury	

Notes for Editors

About ValiRx
ValiRx is a biotechnology oncology focused company specialising in developing novel treatments for cancer and associated biomarkers. It aims to make a significant contribution in "precision" medicine and science, namely to engineer a breakthrough into human health and well-being, through the early detection of cancer and its therapeutic intervention.

The Company's business model focuses on out-licensing therapeutic candidates early in the development process. By aiming for early-stage value creation, the company reduces risk considerably while increasing the potential for realising value. The group is already in licensing discussions with major players in the oncology field.

ValiRx's two classes of drugs in development, which each have the potential for meeting hitherto unmet medical needs by existing methods, have worldwide patent filings and agreed commercial rights. They originate or derive from World class institutions, such as Cancer Research UK and Imperial College.

Until recently, cancer treatments relied on non-specific agents, such as chemotherapy. With the development of target-based agents, primed to attack cancer cells only, less toxic and more effective treatments are now possible. New drugs in this group-such as those in ValiRx's pipeline-promise to greatly improve outcomes for cancer patients.

The Company listed on the AIM Market of the London Stock Exchange in October 2006 and trades under the ticker symbol: VAL

Caution regarding forward looking statements

Certain statements in this announcement, are, or may be deemed to be, forward looking statements. Forward looking statements are identified by their use of terms and phrases such as ''believe'', ''could'', "should" ''envisage'', ''estimate'', ''intend'', ''may'', ''plan'', ''potentially'', "expect", ''will'' or the negative of those, variations or comparable expressions, including references to assumptions. These forward looking statements are not based on historical facts but rather on the Directors' current expectations and assumptions regarding the Company's future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. Such forward looking statements reflect the Directors' current beliefs and assumptions and are based on information currently available to the Directors.

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