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ValiRx PLC
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("ValiRx", the "Company" or the "Group")

VAL201 Clinical Trial Update

Headline results demonstrate VAL201 has potential to be a safe and well-tolerated drug

London, UK ValiRx (AIM:VAL) reports today that it has received headline results from the recently completed Phase 1/2 clinical trial of its lead asset VAL201, for the treatment of advanced prostate cancer, held at University College Hospital (UCLH), London.

The headline results, detailed below, provide a summary of the top-level data of safety and tolerability as well as evidence for disease impact as observed during the clinical trial. Full data and details of from the clinical trial are expected to be received by the Company by end Q4 2020.

Disease Impact - Overall Response Rate 54.5%

Evidence for positive disease impact has been measured using PCWG2 (Prostate Cancer Working Group 2) guidelines. These industry standard guidelines take into account both the primary tumour and metastatic tumours alongside prostate specific antigen (PSA) levels to assess whether the disease has progressed, or whether the patient has responded and halted disease progression. These guidelines provide a more comprehensive measure of disease impact than just primary tumour imaging.

Of the 12 patients dosed with VAL201, 11 patients had sufficient PCWG2-relevant data collected across multiple cycles. 6 of these 11 have been categorised as responding throughout treatment. That is, when the treatment with VAL201 was halted for a defined reason, whether or not the 6 standard cycles had been completed, these patients showed no disease progression by PCWG2 criteria with stable disease.

Safety and Tolerability - no Maximum Tolerated Dose declared

As the first clinical trial of VAL201, safety and tolerability data are of paramount importance.

The headline safety and tolerability results demonstrated only one dose-limiting toxicity event occurred. This was at a maximum dose of 8 mg/kg, with the patient having raised blood pressure (severe hypertension). Following treatment for the raised blood pressure, the patient completed the remainder of the trial.

A Maximum Tolerated Dose has not been determined for VAL201, and all doses remain available for further testing.

No deaths were reported in patients during the clinical trial.

Further minor events listed as likely to be related to the administration of VAL201 are: Injection site disorders in 11 out of 12 patients; fatigue (5/12); dyspepsia (1/12); muscle spasm (1/12); hypertension (2/12); bradycardia (1/12).

Next Steps

During Q4 2020, the Company expects to receive the full Clinical Study Report and will use the complete data to publish the results on the National Institute of Health's (NIH) public database ClinicalTrials.gov, as well as to produce research papers for peer-reviewed publications.

The Company intends to share these results with potential industry partners to evaluate all options for further clinical development of VAL201.

Dr Suzy Dilly, Chief Executive Officer commented: "I am delighted to be able to share these exciting results today, which are an accumulation of a lot of work by the wider team, both within and external to ValiRx. While considering these results it is important to remember that this is only the first clinical trial using VAL201, so this data has been generated using the utmost caution in sequentially dosing patients. Nevertheless, the headline results clearly demonstrate that VAL201 has the potential to be a safe and well-tolerated drug. With this data in hand, future studies will investigate optimal dosing strategies for VAL201 and help confirm these early indications of a positive response rate."

Professor Alan Boyd, Consultant Pharmaceutical Physician and Medical Monitor for the study commented: "Development of effective treatments with low-side effects for patients with prostate cancer who have relapsed after radiotherapy is essential and will improve the lives of patients during treatment. I am pleased to have contributed to a project that has demonstrated such a good safety and tolerability profile while giving the first indications of a favourable effect on the patient's disease."

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

For further information please contact:

ValiRx plc	**Tel: +44 (0) 20 7073 2628**
	www.valirx.com
Suzanne Dilly	Suzanne.Dilly@valirx.com
Cairn Financial Advisers LLP (Nominated Adviser)	**Tel: +44 (0) 20 7213 0880**
Liam Murray / Jo Turner / Ludovico Lazzaretti	
Peterhouse Capital Limited (Sole Broker)	**Tel: +44 (0) 20 7469 0930**
Duncan Vasey / Lucy Williams / Eran Zucker	
Optimum Strategic Communications	**Tel: +44 (0) 20 8148 3040**
Supriya Mathur/ Shabnam Bashir	valirx@optimumcomms.com

About ValiRx

ValiRx accelerates the development of treatments in oncology and women's health to improve patient lives. We provide the scientific, financial and commercial framework to enable rapid translation of innovative science into clinical development.

With our extensive and proven experience in research and drug development, we select and incubate promising novel drug candidates and guide them through an optimised process of development, from pre-clinical studies to clinic and investor-ready assets.

Integrating science and business

We connect diverse disciplines across scientific, technical and commercial domains, with the promise of achieving a more streamlined, less costly, drug development process. We work closely with our selected collaborators and leverage the combined expertise required for science to advance.

Lead candidates from our portfolio are out-licenced or partnered with investors through ValiRx subsidiary companies for further clinical development and commercialisation. https://www.valirx.com/

About VAL201

VAL201 is a short peptide being studied for the treatment of prostate cancer. The peptide structure is inspired by the naturally occurring androgen receptor, and is designed to intercept and prevent the binding of the androgen receptor to SRC kinase - an enzyme implicated in cancerous cell growth pathways. By preventing the androgen-mediated activation of SRC kinase, VAL201 can potentially prevent cancerous cell proliferation (or growth) without interfering with other functions of either the androgen receptor or SRC kinase. This precision method, mimicking a natural process, proposes a high specificity of cancer treatment with a lower side effect profile. VAL201 was licensed from CRT (part of CRUK) in 2010 and developed through preclinical development into this clinical trial in patients with advanced prostate cancer. The study was held at University College Hospital (UCLH), London.

About the VAL201-001 clinical trial

The clinical trial: "A Phase I/II, Dose Escalation Study to Assess the Safety and Tolerability of VAL201 in Patients with locally Advanced or Metastatic Prostate Cancer and Other Advanced Solid Tumours" opened to recruitment in December 2014 and closed in January 2020.

Patients were scheduled for treatment of a once weekly injection of VAL201 in 3 week cycles for a maximum of 6 cycles. A total of 12 patients received at least 1 dose of VAL201.

Patients were eligible if they were: Adult men (over the age of 18) with incurable locally advanced or metastatic prostate cancer who had relapsed following radiotherapy treatment, are in 'watchful waiting' or where a policy of intermittent hormone therapy had been decided. Patients were expected to have no or only mild symptoms relating to their prostate cancer. (ClinicalTrials.gov identifier: NCT02280317)

About Prostate Cancer

Around 48,500 men are diagnosed with prostate cancer in the UK each year[1]. In men, it is the most common cancer in the UK. Prostate cancer is most common in older men. On average each year 35 out of 100 (35%) of new cases are in men aged 75 and over.

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. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

Factors that could cause actual results to differ materially from those in the forward-looking statements include risks relating to unanticipated costs, liabilities or delays; failure or delays in research and development programs; the safety and efficacy of the Company's product candidates and the likelihood of clinical data to be positive and of such product candidates to be approved by the applicable regulatory authorities; unanticipated changes relating to competitive factors in the Company's industry; risks relating to the Company's capitalisation, resources and ownership structure, the availability of sufficient resources for company operations and to conduct or continue planned clinical development programs; the outcome of any legal proceedings; risks related to the ability to correctly estimate operating expenses; risks related to the ability to project future cash utilisation and reserves needed for contingent future liabilities and business operations; risks related to the changes in market prices of the Company's ordinary shares; the Company's ability to hire and retain key personnel; changes in law or regulations affecting the Company; international, national or local economic, social or political conditions that could adversely affect the Company and its business; conditions in the credit markets; risks associated with assumptions the Company makes in connection with its critical accounting estimates and other judgments.

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[1] https://www.cancerresearchuk.org/about-cancer/prostate-cancer/about

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