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

# VAL201 Clinical Trial Full Data Results

***Full dataset confirms VAL201 is a safe and well-tolerated drug candidate***

***Company to host webcast for investors on 8 December 2020 at 2 pm GMT***

**London, UK -** ValiRx plc ("ValiRx", AIM:VAL), a clinical stage drug development company, is pleased to report that it has received the full dataset to be used for the Clinical Study Report from the Phase 1/2 clinical trial of its lead asset, VAL201, for the treatment of locally advanced or metastatic prostate cancer and performed at University College Hospital (UCLH), London. This expands the positive headline results announced on 28 September 2020.

The dataset provides a complete breakdown of the full data of safety and tolerability as well as evidence for encouraging disease impact as observed during the clinical trial. This data will be used to formulate the Clinical Study Report and to report the results on the www.clinicaltrials.gov database. Additional detailed analysis of the results will form the basis of peer-reviewed journal publications.

The full dataset is available to download on the Company website, https://www.valirx.com/our-pipeline/val201 .

Key details of the findings:

**Recruitment Criteria**

- Twelve patients were recruited according to the criteria of having incurable, locally advanced or metastatic prostate cancer with rising PSA[1] (Prostate-Specific Antigen) on three consecutive samples and absent or very mild prostate cancer-related symptoms.
- The demographics and a detailed breakdown of the patients recruited is provided in the download.

**Disease Impact**

- The headline results released in the Company announcement on 28 September 2020 highlighted the response rate of 54.5%, where response was confirmed by a lack of disease progression by PCWG2 (Prostate Cancer Working Group 2) criteria. The dataset now received provides the detailed breakdown of this by providing both the PSA modulation afforded by the treatment, and the tumour response.
- The PSA data, a recognised surrogate of disease progression, shows two patients seeing a decrease in PSA during their treatment period, one of which maintained the decrease throughout the trial. An analysis of the doubling time of patients shows a statistically significant ($p<0.05$, two-tailed Wilcoxon Signed-Rank test for paired samples) increase in PSA doubling time comparing pre-treatment doubling time to post-treatment doubling time. The PSA doubling time would be expected to be unchanged if the treatment was having no impact, so an increase in doubling time demonstrates a slowing rate of growth of PSA levels.
- The tumour response data demonstrates that patients did not have an increase in metastatic lesions during the treatment period, and that metastatic lesions already present did not grow at all in two out of three patients, suggesting a positive influence of VAL201 on the disease.

**Safety and Tolerability**

The further breakdown of the safety data confirms the well tolerated nature of the drug.

Additionally, the initial pharmacokinetic analysis supports the safety profile in confirming the drug is processed and cleared from the body in the manner expected.

The Company expects to publish the data on the National Institute of Health's (NIH) public database ClinicalTrials.gov, as well as produce research papers for peer-reviewed publications.

**Investor Webcast**

ValiRx will host a webcast for investors on Tuesday, 8 December 2020 at 2pm GMT to discuss the findings of the study.

- Prior to the webcast, questions can be submitted online to **questions@valirx.com**
- During the webcast, questions can be submitted through the webcast link below.

To participate, please click on the link below at the designated time:

https://webcasting.brrmedia.co.uk/broadcast/5fc12476b19325729a9d841f

The webcast will be available on demand following a link on the Company's website after the broadcast. This webcast replaces the usual monthly Q&A publication, and a written summary of questions with answers will be provided after the event.

**Dr Suzy Dilly, Chief Executive Officer commented:** "This data demonstrates the potential of VAL201 for further development towards a treatment for patients with prostate cancer. Providing the data breakdown to support and explain the headline numbers is a crucial step and allows us to delve further into analysis of the results. The highly encouraging 54.5% response rate remains unchanged and being able to interrogate the data in more detail allows us to explore the possibilities for optimising the treatment through future trial with partners.

"We continue to share the dataset with potential industry partners who expressed an interest after the headline results were released in September 2020, and I look forward to the discussions that I am confident will arise as we evaluate all options for further clinical development. We would like to thank the team for their hard work and our shareholders for their support."

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014. The Directors of the Company take responsibility for this announcement.

**Ends**

**For further information please contact:**


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**About ValiRx plc**

ValiRx accelerates the development of treatments in oncology and women's health to improve patient lives. We provide the scientific, financial and commercial framework towards enabling 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 aim 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-licensed 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 as a potential treatment for 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[2]. 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] *The PSA test is a blood test used primarily to screen for prostate cancer. The test measures the amount of prostate-specific antigen (PSA) in the blood. PSA is a protein produced by both cancerous and noncancerous tissue in the prostate gland.*

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