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

VAL201 UPDATE

"ValiRx announces that in addition to pharmacokinetic and toxicology data, clinical trial results show VAL201 behaves as predicted in reducing prostate cancer progression"

London, UK., 10 September 2019: ValiRx Plc (AIM: VAL), the clinical stage biotechnology company, today announces that its lead therapeutic compound, VAL201, has thus far and continues to meet all the published endpoints in its first-in-human study. Following the announced allowance of a substantial amendment in March 2019, the later stages of the trial, where subjects are being given therapeutic and supra-therapeutic concentration of VAL201, continues to demonstrate a safe and well tolerated profile. It should be noted that this is cumulative information and the fact that the compound continues to show a toxicological profile at and above clinical concentration is significant.

Beyond the fundamental safety and tolerability endpoints for the trial, the study has provided clear pharmacokinetic information about the uptake, distribution, metabolism and elimination of the compound in humans. The data supports and confirms the findings from preclinical and the earliest stages of human studies and in part explains the reduction in prostate cancer progression as measured by PSA - evidence that is supported from tumour imaging (MRI and CT) in subjects.

The effects of the compound on cancer is related to the tumour's exposure to VAL201, and as expected from the underlying mechanism of action, is a complex relationship to the administered dose. The various amendments to the dosing protocol have allowed this effect to be more fully explored. Further analysis of collected pharmacodynamic samples is progressing and the data is expected to build on this positive outcome to date. The full data set is currently being reviewed and collated. Additional data surrounding the possibility of an effect on metastatic tumour lesions is being collated in the few subjects exhibiting such tumours. Such an effect has been seen preclinically and hints are being observed.

The final stages of this first in-human study has provided the information needed to construct a protocol for the late stage trial directed at determining effective dosing

regimes for clinical use and will explore the full extent of the compound's utility in clinical practice.

This phase I/II trial will be finalised as expected from a regulatory viewpoint while the new VAL201 confirmatory trial is developed and aimed at validating the most effective treatment regime and its particular use in clinical practice. Data relating to the pharmacology, pharmacokinetics and pharmacodynamics will be published as it is collated, verified and submitted.

VAL201 has been developed in collaboration with Cancer Research (CRUK) and is a decapeptide with potential in treating hormone-dependent and hormone-independent prostate cancer, currently a poorly served multi-billion dollar commercial market.

Dr Satu Vanikka, CEO of ValiRx Plc, commented:

"We are delighted that our Phase I/II trial of VAL201 has met its endpoints very well and that we are now able to use our peptide in demonstrating the efficacy of the VAL201 compound as a therapeutic product that has a large role to play in dealing with what is a nasty set of conditions in a better and more patient friendly way."

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

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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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