RNS Number : 9024W
ValiRx PLC
16 December 2019

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

VAL201 UPDATE

"Positive Phase I/II data compiled"

London, UK., 16 December 2019: ValiRx Plc (AIM: VAL), the clinical stage biotechnology company, provides an update on the clinical progress of VAL201, ValiRx's lead Phase I/II therapeutic compound, for the treatment of prostate cancer and other indications of hormone-induced unregulated growth, including endometriosis.

As the Company anticipated in March 2019, the VAL201 trial is coming to a conclusion. The trial data collected to date is undergoing collation and verification, in addition to statistical and scientific analysis. This is prior to its submission to the relevant regulatory authorities. Until regulatory approval has been reached and all the trial data has been verified, limited preliminary observations can be inferred.

The results appear, in advance of full analysis, to indicate that the VAL201 compound has a clear impact on patients with prostate cancer, as measured by PSA - evidence that is supported from tumour imaging (MRI and CT) in subjects. The compound has also shown it is very safe and has a high degree of tolerability, up to a dose that is in excess of the predicted dose and any practical therapeutic concentration.

The results, along with a full statistical and scientific analysis, will be submitted to the relevant regulatory authorities as is required, at which point the detailed results will be made publicly available. However, in the interim, it is intended that the trial's preliminary observations may be presented at various academic conferences, as part of the compound's ongoing reporting and analysis.

Scientific Summary:

- All data collected to date during the clinical trial of VAL201, is currently being reviewed and collated by the data analytics team.
- The data will be secured after it has been entered into the record, collated and verified, whilst some additional data is still to be collected from various providers,

contractors and from patients and then entered into the record.

- Beyond the fundamental safety and tolerability endpoints for the trial, the study is providing accurate pharmacokinetic information about the uptake, distribution, metabolism and elimination of the compound in humans. As such, VAL201 continues to address its endpoints in its first-in-human study.
- A late-stage study designed to determine the overall effectiveness of VAL201 and the most effective therapeutic strategies for its use in disease management, is now possible. This late-stage study will be designed and set up, in parallel to the conclusion of the current early-stage Phase I/IIa trial.

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:

"With prostate cancer reported this month in an academic study as being the most common cancer in men in the UK and with an estimated 1.3 million new cases of prostate cancer occurring worldwide last year**, it is truly exciting to see VAL201 approaching the conclusion of its Phase I/II first-in-man study."*

"I look forward to regulatory approval of the trial data being speedily reached and the opportunity of potentially demonstrating that VAL201 can address this widespread and often fatal disease in men."

Sources:
*https://www.bristol.ac.uk/news/2019/december/prostate-cancer.html

** Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries by Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A in *CA: A Cancer Journal for Clinicians*

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.

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