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ValiRx PLC
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VALIRX PLC

("ValiRx" or the "Company")

UPDATE ON VAL201 & VAL301 CLINICAL AND PRE-CLINICAL DEVELOPMENT PROGRESS.

London, UK., *21 March 2019*: ValiRx Plc (AIM: VAL), the clinical stage biotechnology company, is pleased to provide an update on the development of its therapeutic drugs, VAL201 and VAL301 regarding their clinical and pre-clinical progress.

VAL201

The Company's leading anti-cancer therapeutic, VAL201, is a peptide with a unique mechanism of action, which was first developed by academics partly with support from Cancer Research UK. It is currently in a Phase l/ll Clinical Trial at University College London Hospital ("UCLH") for the treatment of advanced prostate cancer and potentially other indications of hormone-induced unregulated growth.

ValiRx have established that VAL201 is safe and well tolerated at doses of up to 4mg/kg and the Company can report that it has seen primary evidence of the drug's activity in prostate cancer.

Based on these results, the MHRA approved an extension to the trial (announced 18/12/17), allowing for an intra-patient dose escalation of up to 16mg/kg. This segment of the trial is in the concluding stages of its Phase l/ll (announced 17/10/18) and is progressing with patients to establish the maximum tolerated acute dose in Humans (MTD). This part of the study is also further establishing potential efficacy levels and pharmacokinetic / pharmacodynamic profiles as well, providing supporting information with respect to the optimal therapeutic regimes to be tested in the subsequent late stage clinical trials.

An interim inspection of the trial's output indicates that the compound is and continues to perform as predicted from the pre-clinical findings.

On conclusion of the current Phase l/ll trial, the full data set will be analysed by third-party experts and the compound's profile and behaviour will be published.

The completion of the trial is a mandatory milestone prior to permission being given for further pre-market authorisation efficacy studies (Phase II/III).

After reaching a conclusion based upon analysis of the results from this dose-ranging study, the Company will then decide whether to seek a partner or licencing agreement with a pharma company or proceed to a proprietary pivotal Phase IIb/III study.

The results from the trial are expected at the end of H1 2019 and analysis of the data is anticipated to start Q3 2019, following which a full analysis of the results and findings will be published.

The board is currently evaluating the optimum strategies for adding value during the study and commercialising the compound. The Company will keep shareholders and stakeholders informed of progress.

VAL201 has received a number of patent grants in major territories (announced 25/04/18) and these include USA, Europe, Japan and Australia. Additional patent applications are pending in several other countries.

VAL301

VAL301, is derived from ValiRx's lead compound, VAL201 and is currently in late-stage pre-clinical development as a non-invasive, effective treatment for the non-cancerous, but hugely debilitating gynaecological condition, endometriosis.

The compound is derived from VAL201 and its potential therapeutic approach is based on the same mode of action. VAL301 is currently in late-stage pre-clinical development (announced 17/07/18) for the hugely debilitating gynaecological condition, endometriosis, which is characterised by endometrial-like tissue found outside of the uterine cavity. The condition represents one of the major causes of female infertility.

In pre-clinical studies, the compound has been shown to reduce endometrial lesions by up to 50 per cent. and the Company believes it is well placed for further study as a potential treatment. In addition, the Company's pre-clinical studies have also revealed that VAL301's treatment of this hormone-induced disorder is potentially without side effects, such as loss of bone density and fertility (announced 17/07/18). This additional advantage represents a potentially significant further break-through development in the medical treatment for this illness and for other gynaecological conditions.

VAL301 received a US patent grant and receipt of patent allowances covering China and the Russian Federation (announced 17/07/18 and 31/01/19 respectively). These provide protection for the compound in three of the most populous nations in the World.

Dr Satu Vainikka, CEO of ValiRx, commented: *"The pre-clinical and clinical development of the VAL201 compound is very encouraging and from scientific and therapeutic perspectives, we look forward keenly to examining both the trial's results and analysis later this year and the opportunities for VAL201's further development and commercialisation. As with any small biotechnology company such as ValiRx, its patent portfolio and trial results represent its main assets and value drivers. I am delighted therefore with the solid foundation our global patent protection and trial progress represents, which will I am confident be of future benefit to all patients and stakeholders".*

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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