



ValiRx PLC

Quarterly Update on Clinical Developments

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ValiRx Plc

("ValiRx" or "the Company")

QUARTERLY UPDATE ON CLINICAL DEVELOPMENTS

London, UK., 13 September 2016: ValiRx Plc (AIM: VAL), a life science company, which focuses on clinical stage cancer therapeutic development, taking proprietary & novel technology for precision medicines towards commercialisation and partnering, provides a quarterly Q3 update on clinical progress.

VAL201

ValiRx's lead compound, VAL201, continues to perform well in its Phase I/II Clinical Trial in patients with hormone resistant prostate cancer. The Company confirmed in June 2016 that VAL201 was tolerated and had shown a high degree of safety. Since then VAL201 continues to show no drug related significant adverse events and all subjects have tolerated the compound well at the levels of compound administered up to now. The studies continue to show preliminary indications of VAL201 positively effecting subjects' disease profile. These positive indications also extend to include some subjects at an early stage in their therapeutic dose ranging and elevation safety studies.

Additional Clinical Trial Centers are being integrated into the study to assist with the dose expansion stage of the trial. Also an amendment to the trial protocol was filed with the MHRA, the relevant ethics committee and other relevant parties during the period. All changes were agreed. In practice, the amendment means subjects with less advanced cancer can be recruited to the trial. The publicly available details of the changes are to be found on the website www.clinicaltrial.gov, as previously reported.

With the encouraging, independently, generated information that has been gathered during the clinical trial, ValiRx has continued to design the follow-up therapeutic and applicability trial protocols for VAL201 in prostate cancer. This is progressing well and is expected to be completed and in place by the time that the current Phase I/II trial reports.

The Company continues the design of a trial for VAL201's use in treating the debilitating female condition, endometrioses and other endometrial conditions. The associated partnerships - both commercial and technical - are expected to be in place before the final reporting of the current 'safety and tolerability-focused' Phase I/II clinical trial completes.

TRAC

In July, ValiRx sold its subsidiary, ValiRx (Finland) Oy ("ValiFinn"), the company holding its Finnish-based TRAC Technology, to Sovicell Science for Life GmbH, for a cash consideration of €0.8 million. In February 2015, ValiRx had acquired TRAC for a consideration of €75,000. This transaction represented an opportunity to commercialise a part of the Group's portfolio, whilst freeing up resource and management time. ValiRx will continue to have Finnish representation via its other Finnish subsidiary, ValiRx Oy, whilst retaining a royalty-free license to use the technology in its therapeutic developments.

VAL401

Q3 2016 has been an important quarter for VAL401 progress. Full regulatory and ethics approval was received for ValiSeek's clinical trial site at the Medulla Immunotherapy and Chemotherapy Clinic, Tbilisi, to test VAL401 as an oral treatment of late stage non-small cell lung adenocarcinoma. Since these regulatory approvals were received, the site initiation visit has been carried out, introducing the team at Clinical Accelerator to the site, and ensuring the clinicians understand the protocol and recruitment requirements.

The GMP regulatory released doses of VAL401 capsules have arrived on site and the principle investigator will now be able to commence activities to identify, recruit via an informed consent process, screen and finally to dose, monitor and test the patients.

Regulatory stability studies have confirmed that the shelf-life of the released samples should be set at 12 months. Full details of the approved protocol and the up-to-date status of the trial can be found registered on: Clinicaltrials.gov

ValiSeek have confirmed the data management plan for the trial of VAL401 and also contracted with Ariana Pharma, to use the proprietary "KEM" (Knowledge Extraction and Management) patient stratification technology, which has been validated extensively to recognize patterns and relationships and enables full exploitation of complex datasets of small number of patients.

During this quarter, ValiSeek also received notification of a New Zealand patent grant allowance for the key VAL401 patent, including claims covering both the composition of the formulation and its use as a treatment against adenocarcinoma. This first non-US patent grant underlines ValiSeek's intention to create an international project and world-wide commercialisation.

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

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Notes for Editors

About ValiSeek

ValiSeek Limited ("ValiSeek") is a joint venture ("JV") company between ValiRx Plc and Tangent Reprofilling Limited, part of the SEEK Group. ValiSeek was formed to progress the drug VAL401 through its remaining preclinical development and towards Phase II trials for the treatment of lung cancer and other oncology indications

About SEEK

Founded in 2004, SEEK (previously known as PepTcell) is privately-owned and funded, with headquarters in London, UK. SEEK brings safe and low costs medicines to the patients as quickly as possible. It does this by modifying existing medicines to improve their efficacy within current label,

dose and regime, by changing the indication but keeping the dose and dosing regime the same or by creating a new medicine when the previous options are unavailable.

Additional information about SEEK is available on the Company's website located at www.seekacure.com.

ValiRx Plc

ValiRx is a biotechnology oncology focussed 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 Alternative Investment Market ("AIM") of the London Stock Exchange in October 2006 and trades under the ticker symbol: VAL.

This information is provided by RNS
The company news service from the London Stock Exchange

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