Valirx

Bioscience Innovation

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VALIRX plc

CLINICAL STAGE CANCER THERAPEUTICS

WITH COMPANION DIAGNOSTICS

FOR PRECISION MEDICINE

Overview

- **Oncology portfolio of innovative technologies with worldwide rights from leading institutions**

- **Therapeutics, biomarkers and companion diagnostics in development**

- **ValiRx's drug candidate compounds are progressively moving into and through clinical phases**

Key Achievements

- ***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.*** Continuing as planed and expected.
- **Safety, tolerability** of VAL201 **shown (the primary end point).**
- Effects of **VAL201** on subjects following the preclinical pattern.
- **VAL401*** for lung cancer and other oncology indications; clinical trial in preparation.
- Successful preliminary **biomarker developments** with VAL201 for use in clinical trials and beyond.
- Development of **VAL101** is in late stage oncology preclinical studies with partners

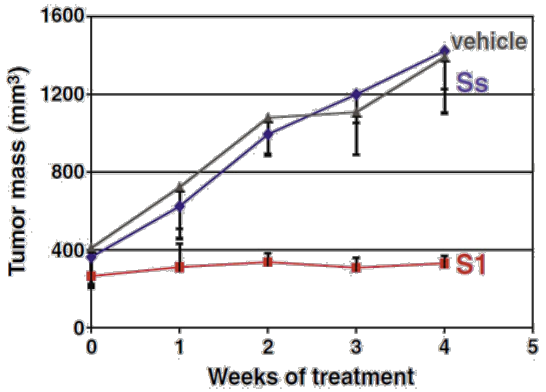
*Being developed through ValiSEEK Limited, a joint venture company in which ValiRx is the majority owner.

VAL201

A NOVEL First in Class Therapeutic

- An unusual decapeptide with some unique properties.
- An Inhibitor of the interaction of activated Androgen Receptor with SRC kinase domain III.
- It is not an androgen inhibitor nor a SRC kinase inhibitor.
- It does not affect the androgen receptor or testosterone production pathways.
- It does inhibit malignant cell proliferation.
- Its specific targeting leads to reduction in tumour proliferation and metastasis thereby reducing Tumour load.

SUPRESSION OF TUMOUR GROWTH



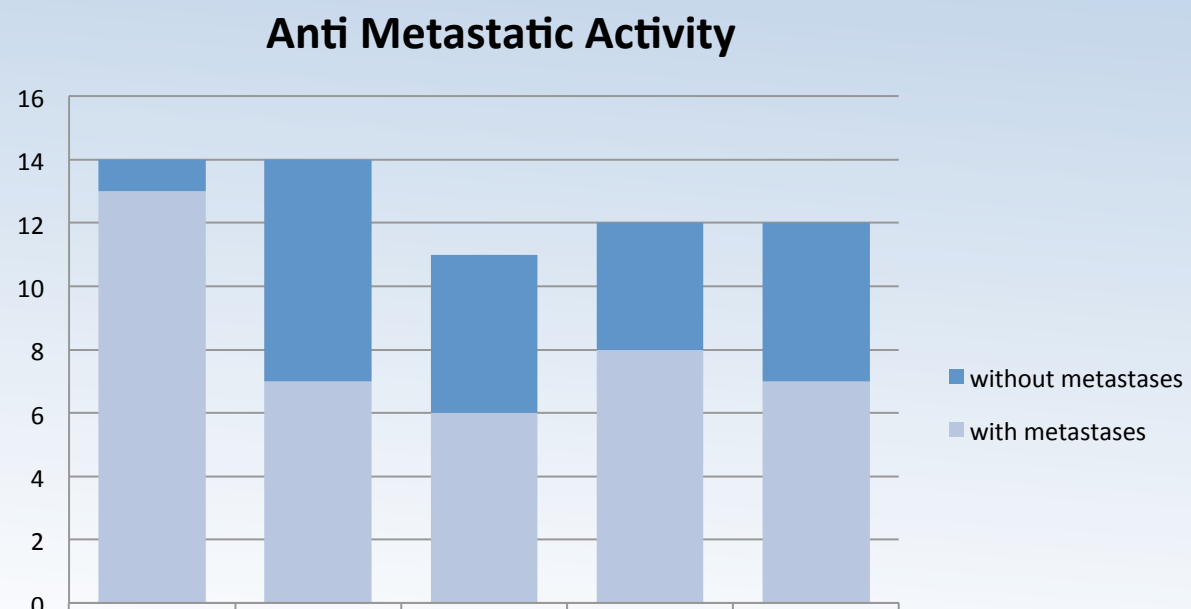
KEY

Ss-NEGATIVE CONTROL
S1 TREATMENT VAL201

- Effective against Hormone refractory tumours and metastasis.
- Clinical phase I/IIa in prostate cancer patients.
- Follow-on indications: E.g., Endometriosis, Breast cancer & Ovarian Cancer.

Prostate cancer market set to expand to $7-9 billion by 2020, due to growing prostate cancer population (25% from 2010 to 2020) .*
(GlobalData 2012)

VAL201 (Cont'd)



	Vehicle	0.04mg/kg	0.4mg/kg	4mg/kg	10mg/kg
without metastases	1	7	5	4	5
with metastases	13	7	6	8	7
%	92.9	50	54.5	66.7	58.3
p-value	-	0.01643	0.03913	0.1174	0.05217

Immunodeficient BALB/c nude mice were allocated to 15-mice groups. PC-3 cells were inoculated into the prostates. SC dosing daily for 28 days

VAL401

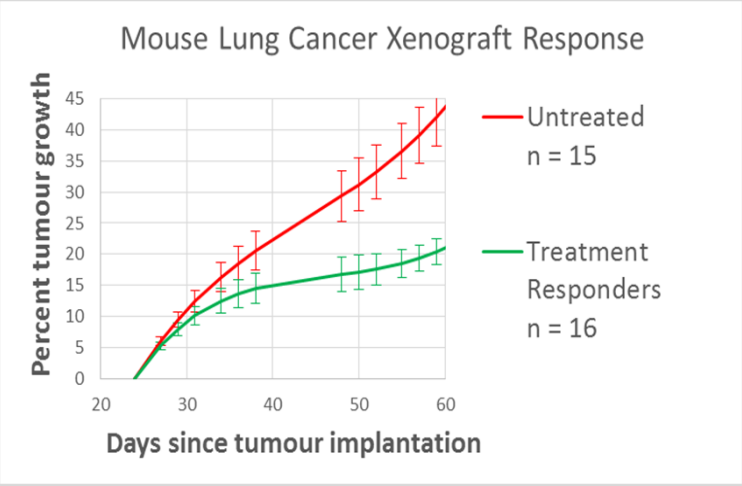
Reformulated drug with completed pre clinical data and with established clinical safety data

- Compared with some other types of cancer, the outlook for lung cancer is not good.
- Lung cancer is one of the more difficult cancers to treat.
- It is often diagnosed at a late stage.
- Many therapies have very significant side effects
- There is a requirement for more effective/ efficacious treatments

VAL401

- A reformulated oral drug
- Has a lower side effect profile compared to most treatments
- Secondary benefits anti-cachexia
- Can be used for late stage patients & in combination at various point in NSCLC progression

SUPPRESSION OF TUMOUR GROWTH SEEN AFTER 7 DAYS OF DOSING



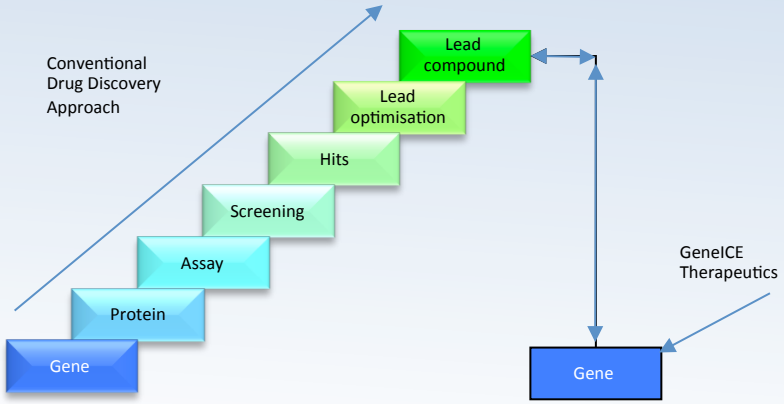
- Clinical Trial is currently being set up for NSCLC
- Suppression of tumour growth after 7 days of dosing
- Data shows VAL401 potential for use against :
  - prostate cancer
  - breast cancer
  - pancreatic cancer

GeneICE – 'Rebellious Genes'

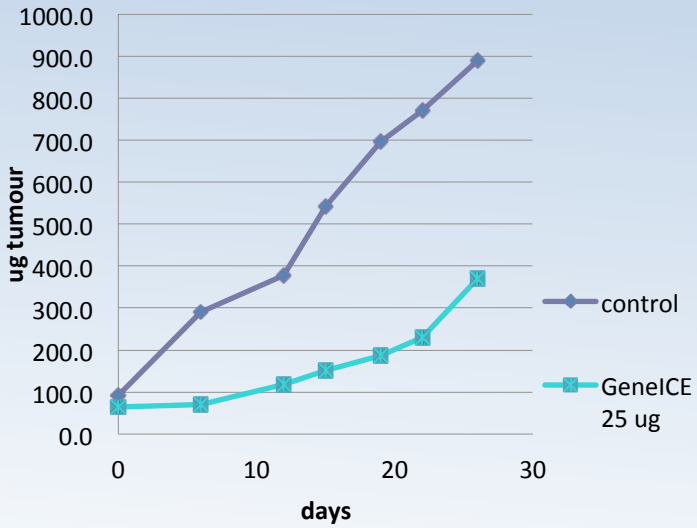
SELECTIVE SILENCING OF "REBELLIOUS GENES"

GeneICE SOLUTION

- A **novel** & **Targeted** "mechanism of action", **Gene silencing not deletion**



TUMOR GROWTH INHIBITION BY VAL101



- Late stage preclinical development with partners.
- Initial targets selected, compounds manufactured optimisation underway.
- Regulatory discussions started.
- Toxicology subject to regulatory requirements planned.

- Proprietary GeneICE technology enables selective silencing and the prevention of over-activity by rebellious genes…..in this case BCL2.
- Down-regulation of over-expressed bcl2 leading to cell death, & tumour growth inhibition.

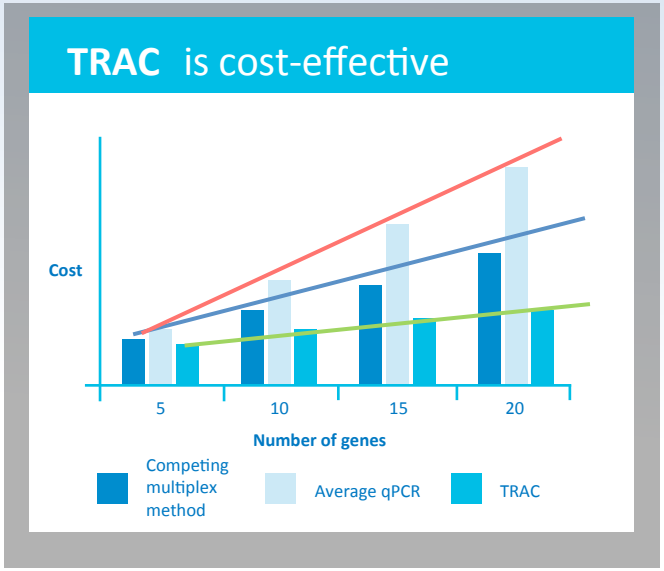
Biomarkers

- Biomarkers for personalised medicine are a hot topic in the pharma industry
- ValiRx is applying its biomarker expertise to the Clinical development of VAL201 and preclinical development VAL101

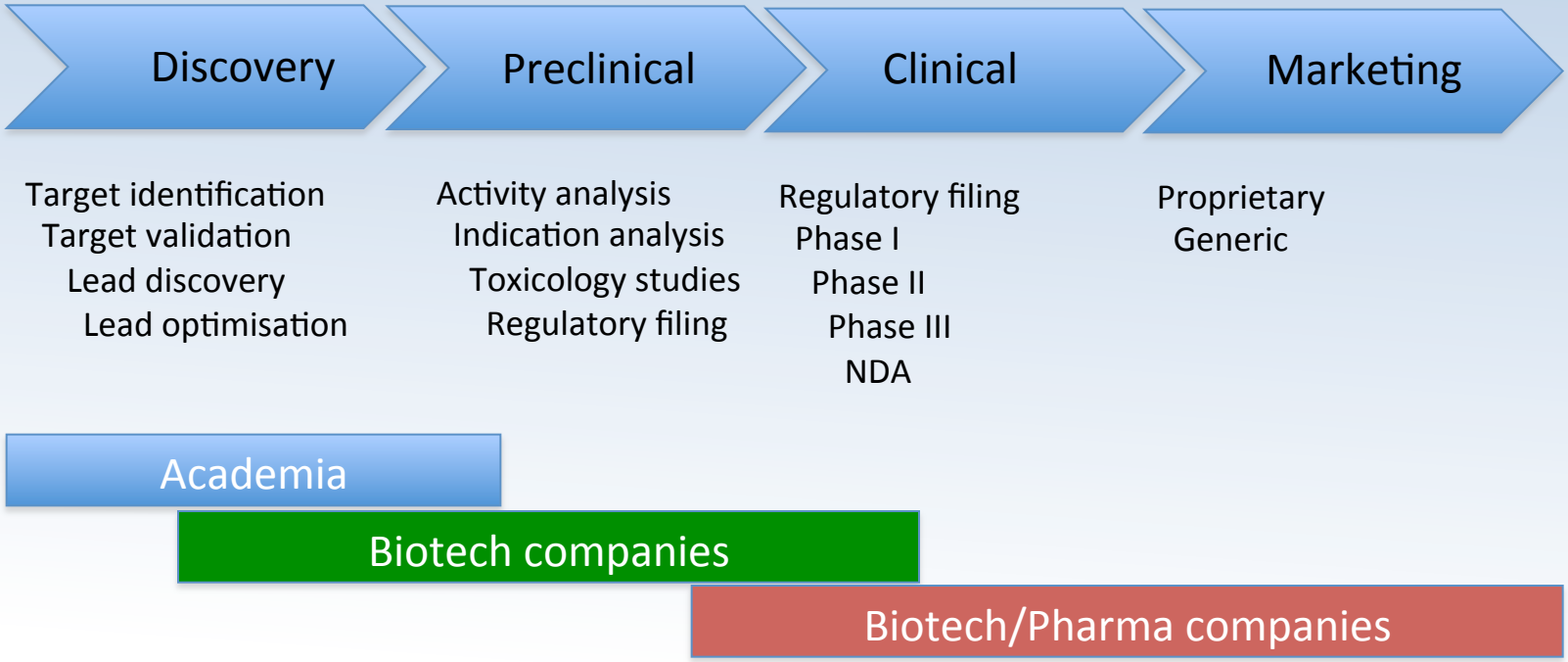
The NAV3 biomarker system.
This proprietary novel NAV3 Cancer Screening Test enables the detection of cancer cells in tissue samples.

TRAC
Gene expression method that enables the screening of hundreds to thousands of samples for dozens of marker genes.

- Effect expressed by genes
- Effect of drugs on genes or gene products
- Rapid testing
- Large number of genes analysed at once
- Low cost



Value Chain



Biotech is the link between discovery and late stage clinical and marketing

Partners

- Cancer Research UK – License for VAL201
- Imperial College London – Development of GeneICE and VAL101
- University College London Hospital – VAL201 Clinical Trial
- Deutsche Krebsforscungzentrum (DKFZ) - Development of VAL101 and GeneICE technology platform
- Eurostars Consortium – Development of VAL101 (two grants second completing)
- Institute Paoli Calmettes - VAL201
- Helsinki and Oulu Universities – Biomarkers, 201, 401
- JV with Tangent LTD – VAL401

Summary

- **VALIRX ADOPTS OUTSOURCING BUSINESS MODEL WITH LEAD COMPOUND IN CLINICAL DEVELOPMENT & A GROWING PIPELINE TO ADDRESS AN EXPANDING MARKET HIGH UNMENT MEDICAL NEEDS**
- The early out-licensing of therapeutic candidates to crystallise value, lower development risk and maximise the likelihood of value creation
- Technologies originate from world class universities and institutes, selective acquisitions, IP and development
- The focus is to partner or out-licence within the phase II development pathway

- **VAL201** :
  - Novel First in Class therapeutic
  - Significant Anti - Tumour efficacy and Anti-Metastatic effect
  - Phase I/II *dose clinical escalation* study ongoing

  Positive initial outcomes have been reported
- **VAL401**:

  Preclinical phase completed
  - Scientific meeting with MHRA to determine point of entry to clinical trials
  - Later stage trials planned and in set up

- **GENEICE**: Epigenetic gene silencing platform advancing through the pre-clinical phase.
- **VAL101:** An initial product candidate selected.
- **TRAC:** A high-content, rapid and cost effective gene expression analysis platform - integration of this platform with diagnostic and service products in development

What Next?

1 Completion of current phase 1/2 clinical Trial for VAL201

- Primary endpoint safety; shown with no limits discovered so far (phase1)
- Secondary end point of tolerability progressing with no issues related to the compound and continuing safety being seen at the predicted MAD (phase 1)
- Tertiary end point compound related effects showing an effect as in the preclinical data so far. (phase 2)
- Protocols and submission paperwork for endometriosis clinical studies

2 First patents recruited for NSCLC trial of VAL401

- Expected 1st half 2016 (phase 2)
- Site visits and commissioning

3 Progress on VAL 101 and completion of second Eurostars Consortium programme

- Partners optimisation activities completing
- Testing of refined compounds in selected tumor models
- Regulatory and formal toxicology planed and reporting of outcomes
- Grant funding

4 Track and Biomarkers

- Development of further panels for endometriosis and other indication with partners

5 Commercial discussions relating to partnering and licensing of compounds

- Discussions with potential licensors of VAL201 ongoing
- Discussions with potential purchasers or licensor's of VAL401 underway
- Continuing discussions surrounding licensing and selling with respect to TRAC and biomarkers

Board of Directors

Mr Oliver de Giorgio-Miller, CHAIRMAN

Oliver has worked for over 30 years with several global pharmaceutical and medical device companies including Schering AG, Hoffman la Roche, Intavent-Orthofix and Photo Therapeutics, a Cancer Research UK company and he has extensive experience advising a number of other early stage biopharmaceutical and medical device companies.

Dr Satu Vainikka, CHIEF EXECUTIVE OFFICER

Satu has many years experience of the biotechnology industry and research, including extensive first hand experience of equity financing, business management and developing life science technology into commercial enterprises.

Dr George Morris, CHIEF OPERATIONS OFFICER

George has over 25 years' experience in biological and medical research, and financial services. As a Research Scientist, He is an author of numerous books and articles on refereed papers, and an inventor of multiple patents.

Mr Gerry Desler, CHIEF FINANCIAL OFFICER

Gerry is a chartered accountant, who qualified in 1968 with a City firm During his time in the City, he has specialised in consultancy work, much of it involving funding and venture capital.

Mr Kevin Alexander, NON-EXECUTIVE DIRECTOR

Kevin is a qualified solicitor in England and an attorney in New York Since leaving the law he has been involved in forming and managing various businesses, both private and public. He has an MA in law from Cambridge University.

Mr Seppo Mäkinen, NON-EXECUTIVE DIRECTOR

Seppo has more than 25 years of senior advisory and executive experience in board level strategic leadership and venture capital management on life science development.

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