ValiRx

ValiRx Plc is a life science company, which focuses on clinical stage cancer therapeutic development, taking proprietary and novel technologies and products for precision medicines towards commercialisation and partnering.
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Overview

• Portfolio of innovative technologies and therapeutics

• Precision medicine: the foundation of future cancer therapeutics
  – Cancer is an extremely heterogeneous disease. Precision medicine of cancer focuses on matching the most accurate treatment for each individual. Thus avoiding the “one-size-fits all”
    • (nature partner journals, 2017)

• Worldwide development and commercial and patent rights

• Clinical assets in development
  ▪ VAL201 in clinical phase I/II dose escalation and expansion
  ▪ VAL401 primary results completed from clinical phase II efficacy study

• Pre-clinical asset pipeline:
  ▪ VAL301, a new formulation of VAL201 for treatment of endometriosis
  ▪ VAL101, a Bcl-2 gene silencing & gene editing compound derived from proprietary GeneICE platform
  ▪ GeneICE platform technology for designing compounds for controlling “rebellious” genes

www.valirx.com
Partners

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

• Reformulation of Risperidone in a specific lipid formulation in gelatin capsules.

• Recently completed Phase II clinical trial study of end-stage lung cancer patients

• When treated with VAL401, the patients show statistically significant overall survival and improved quality of life over un-recruited patients

• Protocol for Phase III under preparation, results from the initial trial will inform design of a Phase III pivotal trial. Anticipated approx. 200 patients required.

• Expected regulatory filing for trial approval 2018, multi-centered, multi-national trial – to include FDA and/or EMEA territories

• Patents granted in US (5 patents), AU, NZ and pending in several other territories

• Key near-term decision points:
  – Which patient market to target (end stage, earlier disease or combinations)
  – Choosing the right partner with the right expertise to develop the project
  – Ensuring maximum patient benefit and value to shareholders
**VAL401 - Experimental Results**

*In Vivo* efficacy (lung cancer xenograft)

- Treatment with VAL401 demonstrated at least a 50% reduction in the rate of lung cancer xenograft tumour growth over untreated mice.

- The data represents the percentage of tumour growth during the dosing period, which was 24 – 42 days following tumour implantation.

- H2228 cell line derived from human NSCLC adenocarcinoma.

![Graph showing mouse lung cancer xenograft response](image-url)
VAL401 – Clinical Results

Kaplan-Meier Survival Graph showing length of time in days of patient Overall Survival from time of first lung cancer chemotherapy treatment as a proxy for date of diagnosis.
VAL201

• Precision targeting for hormone induced cancers and abnormal growth, including prostate, breast and ovarian cancers, as well as endometriosis

• The mode of action indicates the minimising of side effects associated with several current therapies

• Phase I/II clinical trial for prostate cancer ongoing with UCLH

• Treatment is safe, well tolerated and no adverse events or dose limiting toxicity have been shown. Preliminary efficacy was seen with relatively low doses.

• Based on encouraging positive results, MHRA have approved extension and upgrade of the trial so as to be able to expand intra patient dosing regime and frequency to more accurately reach the full anti-cancer impact.

• Approval gives flexibility in deciding next stages, potential final approval design for the treatment and suitability for commercial strategy of potential partner

• Patent grants allowed in US, EU, JP and AU and applications pending in several other territories.
Inhibition of Xenograft development in peptide treated animals Vs scrambled peptide and vehicle.

- The proliferation status of cancer cells was significantly decreased in LNCaP tumours treated with the peptide.

- In addition (TUNEL)-positive nuclei were also significantly increased, indicating that the peptide treatment acts on both proliferation and apoptosis.
## VAL201 Clinical Results to Date

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Dose</th>
<th>Mean age</th>
<th>Mean days under dosing</th>
<th>Treatment related Adverse Events</th>
<th>Effect on PSA</th>
<th>Imaging response Study end</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.5mg/kg</td>
<td>71</td>
<td>191</td>
<td>G1 rash, G1 fatigue</td>
<td>2.8X longer doubling time</td>
<td>Stable Disease/Progressive Disease</td>
</tr>
<tr>
<td>2</td>
<td>1.0mg/kg</td>
<td>63</td>
<td>126</td>
<td>G1 rash</td>
<td>unchanged</td>
<td>Stable Disease</td>
</tr>
<tr>
<td>3</td>
<td>2.0mg/kg</td>
<td>76</td>
<td>68</td>
<td>G1 rash, G1 fatigue</td>
<td>unchanged</td>
<td>Stable Disease/Progressive Disease</td>
</tr>
<tr>
<td>4</td>
<td>4.0mg/kg</td>
<td>70</td>
<td>88</td>
<td>G1 rash, G1 fatigue</td>
<td>Reduction 0-40% mean 30%</td>
<td>Stable Disease</td>
</tr>
<tr>
<td>6</td>
<td>8-16 mg/kg</td>
<td>Escalation and expansion approved by MHRA, patient recruitment ongoing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VAL201 Anti-Metastatic Activity

Anti-Metastatic activity

<table>
<thead>
<tr>
<th></th>
<th>Vehicle</th>
<th>0.04mg/kg</th>
<th>0.4mg/kg</th>
<th>4mg/kg</th>
<th>10mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>without metastases</td>
<td>1</td>
<td>7</td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>with metastases</td>
<td>13</td>
<td>7</td>
<td>6</td>
<td>8</td>
<td>7</td>
</tr>
</tbody>
</table>

| %     | 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
VAL301

• Same active pharmaceutical ingredient as VAL201, which has a good clinical safety and tolerability profile

• Val301 is being developed for Endometriosis, which is a painful and chronic gynaecological condition, estimated to affect about 1 in 10 women of reproductive age in UK alone

• In pre-clinical trials, VAL301 treatment has been shown to reduce endometrial lesions, whilst also indicating that the treatment should not affect bone density and fertility, problems experienced by several current medical treatments

• Currently completing the pre-clinical package before advancing to clinical trials, focusing on developing non-invasive, effective and better tolerated treatments for this condition

• Given the mechanism of action, potential to investigate endometrial cancer.
GeneICE- VAL101

Selective “Rebellious Gene” Gene Silencing and Editing Platform

- Proprietary GeneICE technology platform enables selective gene targeting and silencing
- Lead compound targets BCL2 gene, which is associated with several cancers
- Natural mechanism for gene activity control
- In pre-clinical development with partners, initial cancer targets selected
- VAL101 has shown Bcl-2 binding and gene downregulation, cancer cell death analysis ongoing
- Toxicology/Regulatory discussions started
- Programme has received two consecutive Eurostar grants based on scientific and commercial assessment

GeneICE Solution
A novel & Targeted “mechanism of action”

Structure of VAL101

First Generation G1
Gene finding/binding domain
Chemistry and size optimisation
Link chemistry
Linker
Second Generation G2
Gene finding/binding domain
Repressor recruiting domain
Nucleic acid
Peptide
Repressor recruiting domain
NLS
Market Forecasts

• By 2025
  – Prostate cancer $18.4 billion
  – Non-small cell lung cancer $12.2 billion
  – Endometriosis expected to surpass $2 billion
  – Genome editing $8.1 billion

• By 2022
  – Global cancer therapeutics market $172.6 billion
  – Cancer mortality is now the first or second leading cause of death in most high-income countries
    • (Businesswire, Grandview research, Pharmrpro, PR Newswire)

• People live longer, better and earlier diagnostics, other factors?

• ...“more licensing deals deals from Big Pharma will produce valuable health solutions going forward and these companies are positioning themselves for growth by diversifying to increase their market share in particular therapeutic areas”...
  • GlobalData Healthcare, 2017
Summary and Future

The recent achievements and progress with all projects have clearly generated asset value and been of benefit to potential patients

1. **Lung Cancer Clinical trial of VAL401**
   - Positive primary data shows increased survival and quality of life
   - Results from the initial trial will inform design of a Phase 3 pivotal trial, expected regulatory filing 2018
   - Deciding the best way for the next stage

2. **Prostate Cancer Clinical Trial for VAL201**
   - Compelling early clinical data in late stage prostate cancer
   - Acceleration of clinical dose escalation study to see further enhanced therapeutic effects
   - Explore other potential indications with partners

3. **Progress on preclinical pipeline - VAL 101 and VAL 301**
   - **Val 101**
     - Continued pre-clinical progress and toxicology
     - Select cancer indication, possibly pancreatic and other indications with partners
   - **Val 301**
     - Validation, additional genetic toxicology, clinical trial preparation, partner selection

5. **Commercial discussions relating to partnering and licensing of compounds ongoing**

I very much look forward to the future
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