Valirx

Bioscience Innovation

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Overview

- A primary focus on oncology therapeutic development, taking proprietary and novel technology for precision medicines to commercialisation
- A portfolio of innovative technologies with worldwide rights from leading institutions
- Two therapeutic assets in clinical trials

Key Achievements

VAL201

- ***A Phase I/II dose escalation study to assess safety and tolerability of VAL201 in the treatment of prostate cancer and other solid tumours***
- The Phase I/II Clinical Trial of VAL201 has confirmed that the compound was well tolerated and safe, with no serious adverse events being reported.
- Post period studies continue to show preliminary indications of VAL201 efficacy

VAL401*

- ***Phase II clinical study*** for lung cancer
- Open label trial in lung cancer patients – Screening and recruitment underway

VAL301

- VAL301 in development - reformulation of VAL201 for new indication, endometriosis

VAL101

- Development of **VAL101** (using the GeneICE Platform) is in late stage oncology pre-clinical studies with partners.

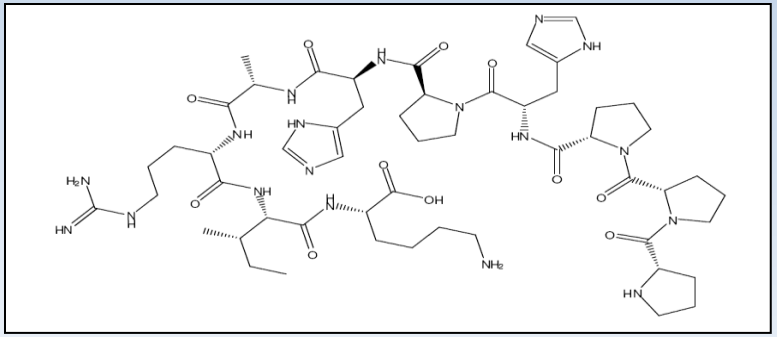
*Being developed through ValiSEEK Limited, a joint venture company in which ValiRx is the majority owner.

What is VAL201?

H-Pro-Pro-Pro-His-Pro-His-Ala-Arg-Ile-Lys-OH

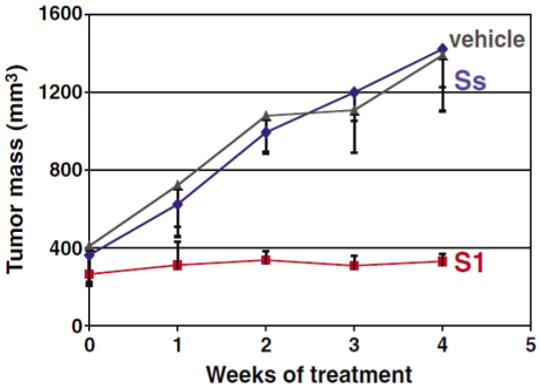
A NOVEL First in Class Therapeutic

A decapeptide with some unique properties



Molecular Weight (free base)	1149.3481
Monoisotopic Mass (free base)	1148.6567
Molecular Formula	C55H84N18O11
Melting Point	186° C
Solubility	Freely soluble in water
pH of a 1% solution in water	5.67
Salt Form	acetate

SUPRESSION OF TUMOUR GROWTH
Pre-clinical results



- **Effective** against tumours and metastasis
- Only inhibits malignant cell proliferation.
- In vitro nM concentrations of VAL-201 inhibits the androgen-induced association between the AR/ER and Src, Src/Erk pathway activation, cyclin D1 expression and DNA synthesis without interfering in the receptor-dependent transcriptional activity.

First in Human VAL201 Clinical Trial An initial appraisal

Methods

- An accelerated titration, open label, dose-escalating trial design to identify a maximum tolerated/administered dose (MTD/MAD).
- VAL201 is given subcutaneously on Days 1, 8, 15, q21. on each cycle (6 cycles per subject)
- Expansion to a 3+3 design occurred at dose level (DL) 3.
- Dose limiting toxicity (DLT) was assessed during Cycle 1 and safety evaluations were conducted weekly

First Dose Escalation Patient Characteristics

- Eight patients with a Median age of 71 years with prostate cancer recruited, to 4 dose levels (0.5mg/kg n=1; 1.0mg/kg n=1; 2.0mg/kg n=3; 4.0mg/kg n=3)
- Patients had either PSA relapse without radiological evidence of disease (2/8), locally advanced disease (1/8) or metastatic disease (5/8), 3/8 patients had castrate resistant disease prior to recruitment.

Patient #	Dose cohort	Age	ECOG PS	Disease status	Castrate sensitivity	# Prior hormonal therapy	# Prior chemo
101-001	0.5mg/kg	71	0	metastatic	resistant	2	0
101-003	1.0mg/kg	63	0	locally advanced	sensitive	0	0
101-005	2.0mg/kg	79	1	metastatic	resistant	3	1
101-006	2.0mg/kg	70	0	metastatic	sensitive	1	0
101-007	2.0mg/kg	81	0	metastatic	sensitive	0	0
101-008	4.0mg/kg	68	1	metastatic	resistant	3	1
101-009	4.0mg/kg	82	0	PSA relapse	sensitive	1	0
101-011	4.0mg/kg	60	0	PSA relapse	sensitive	0	0

First in Human VAL201 Clinical Trial Initial appraisal Results

Pharmacokinetics (PK)

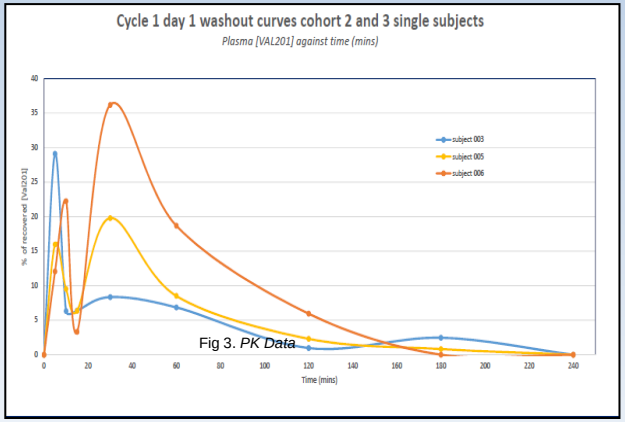
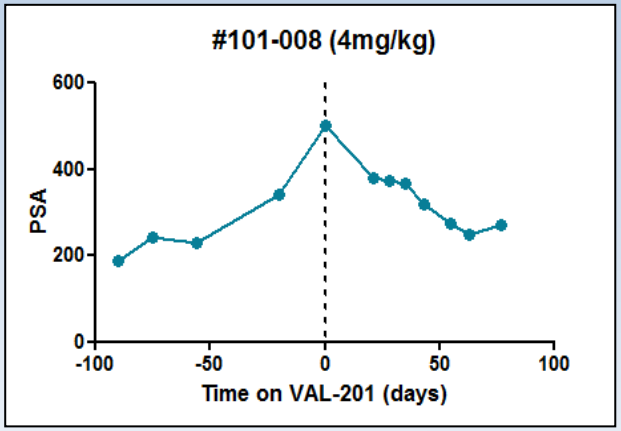


Fig 3. *PK Data*

- **Samples taken at specific time-points over a 24 hour period to determine VAL-201 concentration-time profile; shown here to 4 hours post administration**
- **PK profiles from patients treated at 1.0mg/kg and 2.0mg/kg are suggestive of a dose effect in Cmax and AUC**

Preliminary Efficacy (PSA) levels



- ***PSA response data for pt # 101-008) with metastatic castrate resistant prostate cancer, a >30% PSA response on low dose and low frequency of dosing.***

Adverse Events (safety and Tolerability)

Patient #	Dose cohort	Days on trial	Adverse Events	PSA doubling pre-trial (months)	PSA doubling on trial (months)	Imaging response
101-001	0.5mg/kg	191	G1 rash, G1 fatigue	2.8	7.5	SD
101-003	1.0mg/kg	126	G1 rash	13.3	6.1	SD
101-005	2.0mg/kg	85	G1 fatigue	1.6	2.2	PD
101-006	2.0mg/kg	55	G1 fatigue	1.9	1.6	SD
101-007	2.0mg/kg	64	G1 rash, G1 fatigue	12.5	8.2	SD
101-008	4.0mg/kg	77	G1 rash, G1 fatigue	2.9	-2.5	SD
101-009	4.0mg/kg	119	G1 rash, G1 fatigue	2.9	7.5	NE
101-011	4.0mg/kg	21*	G1 rash	8.9	NA	NA

- **No DLTs have been observed to date**
- **VAL-201 is well tolerated**
- **Injection site rash/ reaction (6/8) and fatigue (6/8) are the only drug related AEs noted to date**
- **Median treatment duration 85 days (21-191)**
- **4 patients had an improvement in PSA doubling time on study**

Conclusions

- **VAL201 is well tolerated with early signs of activity in advanced prostate cancer at sub MAD/MTD dosing**
- **No DLTs have been observed**
- ***Excellent safety and tolerability & Efficacy indicated in clinical subjects***

VAL301

The Company continues with the design of a trial for VAL201's use in treating the debilitating female condition, endometrioses and other endometrial conditions.

- Proposed reformulation into oral format of VAL-201
- Pre-clinical data suggests effect on endometriosis, whilst maintaining bone density and fertility.
- 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.

VAL401

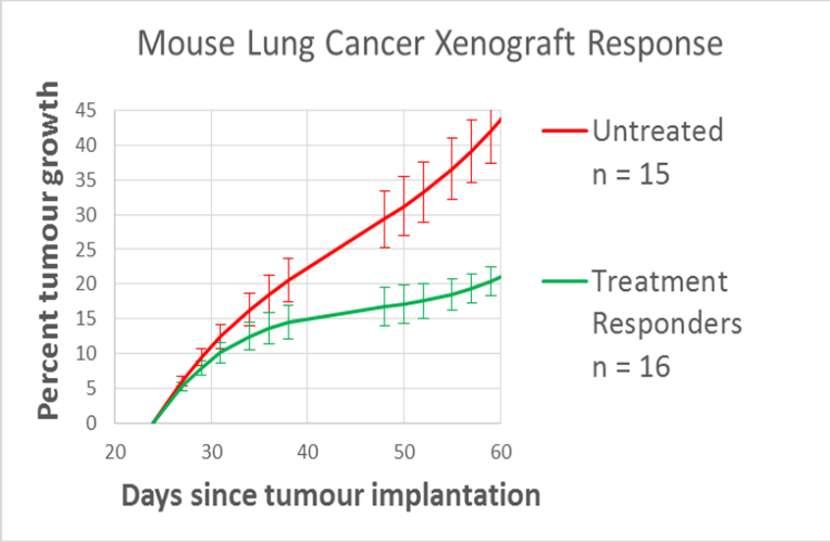
Reformulated Risperidone with pre-clinical anti-cancer activity.

APPROVED FOR A PHASE II CLINICAL TRIAL IN TBILISI, GEORGIA .

- To treat late stage non small cell lung cancer patients.
- Looks for anti-cancer activity and improvements in quality of life.
- Safety, tolerability and pharmacokinetics will also be measured.

VAL401

- A reformulated oral drug – lipid or "oily" capsule
- Secondary benefits anti-cachexia, anti- nausea and anti-Insomnia
- Possible use in combination



- **Preclinical data shows VAL401 also available in:**
  - prostate cancer
  - breast cancer
  - Pancreatic cancer

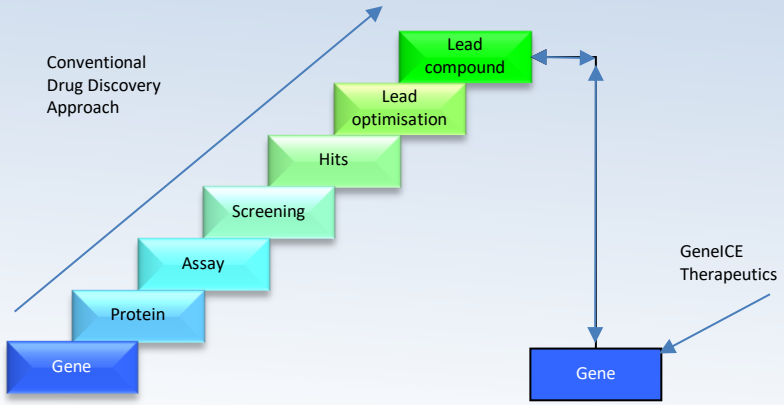
VAL401 has a different mechanism of action compared to current cancer treatments - cross-resistance deemed unlikely

GeneICE- VAL101

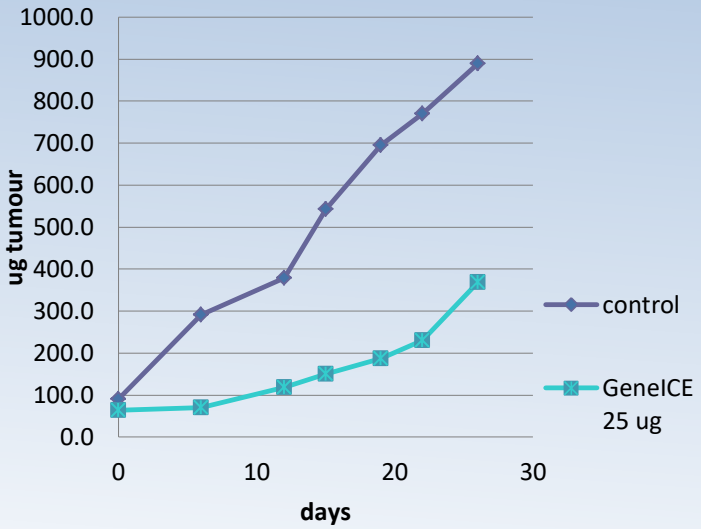
SELECTIVE GENE SILENCING PLATFORM FOR "REBELLIOUS GENES"

GeneICE SOLUTION

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



TUMOR GROWTH INHIBITION BY VAL101



- In 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 platform 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.

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 Reprofiling Limited – VAL401
- And others

RECENT ONCOLOGY DEALS

Delenex Therapeutics AG	Acquired by Cell Medica (undisclosed) – share swap	07/12/2016
Cormorant Pharmaceuticals	Acquired by Bristol-Myers Squibb - $520 Million	05/12/2016
Alize Pharma II	Acquired by Jazz Pharma - €18 Million	11/05/2016
Redox therapies	Acquired by Juno therapeutics - $10 Million in cash upfront - and commercial milestones	14/07/2016
Pharmacyclics	Acquired by AbbVie for $21 Billion (one of the largest deals in the sector in the last 15 years)	05/03/2015
Medivation	Medivation acquired by Pfizer for reportedly close to $14 Billion deal – Prostate cancer asset	22/08/2016

Summary

- ValiRx looks for the early out-licensing of therapeutic candidates to crystallise maximum value with lower development risk
- Technologies originate from world class universities and institutes
- 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 escalation clinical trial*** -

VAL301:

- Proposed reformulation of VAL201 to treat chronic female condition, endometrioses and other endometrial conditions.
- Pre-clinical data suggests effect on endometriosis, whilst maintaining bone density and fertility.

VAL401:

- Phase II clinical trial
  - To look for anti-cancer activity and improvement in quality of life
- VAL401 also has potential for use against prostate, breast and pancreatic cancers

GENEICE – VAL101 : Epigenetic gene silencing platform advancing through the pre-clinical phase

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