Non-Independent Research
MiFID II Exempt

5th October 2020

Stock Data

Ticker	VAL LN
Share Price:	26.8p
Market Cap:	£17.1m

Source: London Stock Exchange

Company Description

Clinical-stage life sciences company focused on the development of treatments in oncology and women's health

Share Price Chart (p)

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FLASH NOTE

ValiRx plc*

VAL.L ***CORP**

Headline results from VAL201 trial

Key points

- On September 28th ValiRx announced headline results from its Phase 1/2 clinical trial of lead asset VAL201, for the treatment of advanced prostate cancer.
- Headline data broadly demonstrated the drug's safety and tolerability.
- Evidence for positive disease impact was also measured, with 54% of relevant patients demonstrating a response.

These headline results represent a significant milestone for ValiRx, in that the Company's lead asset VAL201 has shown an early efficacy signal in treating refractory advanced prostate cancer.

While these results were from an early stage trial, the data indicates that the drug warrants further clinical investigation.

Although certain adverse events were reported, it is worth noting that this is the first clinical trial using VAL201, and consequently dosing has not yet been established. As such, further work will investigate optimal dosing strategies to reduce any side effects and support the drug's potential efficacy.

ValiRx indicated that once the full results are available in Q4-2020, the Group intends to share them with potential industry partners to evaluate options for further clinical development.

** SP Angel provides Research Services to ValiRx and therefore this information should be viewed as a Marketing Communication.*

Headline results from the VAL201 trial showed that 54% of relevant patients demonstrated a positive response to the treatment. Although this was an early stage study, the data indicate that further clinical investigation of the drug is warranted.

Early efficacy signal

In the trial, disease impact was measured using what's known as PCWG2 (Prostate Cancer Working Group 2) guidelines. These guidelines allow for the measurement and comparison of multiple disease progression markers over time, including primary and secondary tumour size, as well as other biomarkers such Prostate Specific Antigen (PSA) levels, which can indicate changes in a patient's prostate cancer. These markers allow for calibrated measurement of disease progression.

The trial results are summarised below:

- 12 patients were dosed with VAL201
- 11 patients had sufficient PCWG2-relevant data collected
- 6 of these 11 (54%) were deemed to have responded to treatment with VAL201
- patients were categorised as responding to treatment when they showed no disease progression by PCWG2 criteria during the course of the trial

Although the trial was an early stage study, designed primarily to asses safety and tolerability, the data warrant further investigation of VAL201's possible effect. Further clinical studies would require larger patient numbers and a control group.

Safety and tolerability

The headline results flagged a patient having severe hypertension while in the trial. In our discussions with the ValiRx management team we understand that this patient already had a history of hypertension and that following treatment for the raised blood pressure, the patient completed the remainder of the trial. Moreover, the patient completed the trial at the maximum drug dose (8mg of VAL201/kg) administered in the dose-escalation study.

Given that a Maximum Tolerated Dose has not yet been determined for VAL201, all doses remain available for further testing. As such, further studies are expected to establish optimal dosing strategies for the drug to maximise its potential positive effects while mitigating against any unwanted side effects.

Prostate cancer, a major health burden

There were 1.3 million new prostate cancer cases globally in 2018, making it the fourth most commonly occurring cancer overall and the second most commonly occurring cancer in men. Although radiotherapy and hormone therapies have proven to be effective, there remain limited options to patients whose cancers no longer respond to these treatments. Consequently, potential novel treatments, such as VAL201, are much needed for patients with prostate cancer which has returned after radiotherapy.

Full clinical report expected in Q4

ValiRx expects to receive the full Clinical Study Report in Q4-2020, which will provide far more data on the trial and allow the company to evaluate next steps for this programme, including potential plans for further clinical development with possible partners.

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Buy - Expected return >15%

Hold - Expected return range -15% to +15%

Sell - Expected return < 15%