Evaluate Vantage

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VTV celebrates a double positive

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Yesterday’s clinical study success has underlined VTV's status as a small-cap bet on Alzheibetes.

Sometimes things go well for biotechs, and occasionally they work out brilliantly. VTV Therapeutics’ pivot to type 1 diabetes two years ago was rewarded with a phase II study win yesterday, prompting a 52% share price surge.

As luck would have it VTV has a second reason to celebrate: its decision not to abandon Alzheimer’s entirely has played straight into a space where Novo Nordisk has recently been drumming up investor interest. While VTV is still well off the highs it had once enjoyed the pieces are in place for a comeback.

That comeback could see VTV capitalise on the putative link between Alzheimer’s disease and diabetes that Novo’s GLP-1 analogue diabetes Victoza will soon test through Imperial College’s Elad trial, whose readout is due imminently (*Novo Nordisk’s quiet entry into the year of Alzheimer’s, January 20, 2020*).

At the heart of the hypothesis lies the claim that neurodegeneration is linked to low insulin and insulin resistance. However speculative this might be, Novo’s stock is up 12% year to date, a spike some analysts have put down to excitement about the Elad readout.

Elevage

For VTV more evidence should emerge in the first half of next year, when the phase II Elevage trial of its Rage inhibitor azeliragon will yield topline results.

Elevage enrols subjects who have mild Alzheimer’s as well as and impaired glucose tolerance, and VTV claims that Rage’s biology has been implicated in diabetic complications as well as cognitive impairment. It was started after a post-hoc analysis of the phase III Steadfast trial in which azeliragon had crashed in Alzheimer’s without diabetes.

In the meantime the company’s investors can celebrate yesterday’s win in part two of the Simpliciti-T1 study of another pipeline asset, the oral glucokinase activator TTP399, in 85 type 1 diabetes subjects on background insulin. Part one of Simpliciti-T1, in 19 patients, had read out positively, but the real test was part two.

VTV appears to have hedged its bets, carrying out two primary efficacy analyses, the less stringent of which excluded 13 non-complying patients who had increased their bolus insulin. This showed a 0.32-point reduction in 12-week HbA1c versus placebo, with statistical significance (p=0.001).

In fact, a stringent assessment of all subjects also hit statistical significance, VTV said, at p=0.03; the numerical HbA1c change was not disclosed. Patients' daily time in range, an important secondary endpoint, was also improved versus placebo, and there was no severe hypoglycaemia in the active cohort.

Pivotal start

VTV says it will in the second half move to start a pivotal TTP399 programme comprising two six-month studies at an estimated cost of up to $100m. The group had just $2.4m in the bank in September, so an equity raise is likely, though it says it also wants to talk to others about co-development or pure licensing.

Given the dearth of novel type 1 diabetes treatments – patients basically have to rely on insulin – the positive clinical result should be expected to generate interest. This is in stark contrast to type 2 diabetes, which is extremely crowded and controlled by big pharmaceutical companies.

TTP399 had also been in development for type 2 disease, but this was de-emphasised – another move that today looks to have been shrewd.