Evaluate Vantage

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Veru gets a big Covid boost

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But full data will be needed to confirm that sabizabulin is a real contender.

Veru has shown that it is still possible to make huge gains off the back of Covid data. According to the company its microtubule inhibitor sabizabulin managed to cut the risk of death in high-risk hospitalised patients, sending the group's stock up 182% yesterday.

True, this is a niche in which many other drugs, including the monoclonal antibodies and Merck & Co's molnupiravir, have failed to make a mark. But there is reason to be cautious about Veru's claims, given its previous attitude towards data disclosure. And there is also the question of market size, given the various options available and the fact that vaccines have cut hospitalisation rates.

Stopped early

For now, Veru is only giving the headline findings from the pivotal study, which was stopped by its independent data-monitoring committee for "overwhelming evidence of efficacy" in the first 150 subjects enrolled.

Here, at least, the company appears to have gone one better than the likes of Synairgen and Kiniksa, which have seen their projects fail in the hospital setting in recent months.

The primary endpoint of the sabizabulin trial was the proportion of patients who died by day 60: 20% versus 45% in the sabizabulin and placebo arms respectively. This gave a relative reduction in death of 55% with a p value of 0.0029 in the intent-to-treat population, Veru said.

The exact population is relevant because Veru used a modified intent-to-treat analysis when it claimed a win in its 39-patient phase 2 Covid study, crucially excluding from the sabizabulin cohort a patient who had experienced respiratory failure. That trial primarily looked at the proportion of patients alive without respiratory failure; there was an intriguing reduction in deaths, a secondary endpoint.

The small numbers of patients in both studies could give investors pause. It will now be up to the FDA and regulators around the world to decide whether sabizabulin passes muster.

On Veru's side will be unmet need: the 45% mortality rate in the placebo arm attests that the patients enrolled in this study, who came from the US as well as Brazil, Colombia, Argentina, Mexico, and Bulgaria, were very sick indeed. And these patients were already receiving standard of care, including dexamethasone, Gilead's Veklury, anti-IL-6 antibodies such as Roche's Actemra and Jak inhibitors like Lilly's Olumiant.

“No imbalances”

Veru seemed to scotch any worries that these other treatments might have skewed results: during a conference call yesterday, company execs pointed to an even balance between the treatment and placebo groups in terms of background therapy, as well as age, sex and disease severity.

They did not give a breakdown of the different variants involved in the trial, saying these data were still being analysed, but added that Delta and Omicron were present in both study groups.

Veru believes that, by disrupting microtubules, sabizabulin perturbs the “highways” along which the coronavirus is transported within cells; this could make it a variant-agnostic therapy, the company reckons. The project is also being evaluated in cancer.

If Veru can get sabizabulin to market in Covid it will then have to worry about manufacturing and distribution. Execs did not rule out signing up a partner to help here, but this could be a daunting task for a small company.

Veru's task will be doubly difficult if Pfizer’s Paxlovid can show a benefit in hospitalised patients in a new arm of the UK’s Recovery trial. Veru’s Mr Steiner made much of sabizabulin being a once-daily pill, versus Paxlovid’s three-tablet, twice-daily regimen – but even big players have had trouble challenging Pfizer’s dominance in Covid.

Selected ongoing trials of Covid-19 therapies in hospitalised patients

Company	Project	Mechanism	Route of admin	Trial details
Foresee Pharmaceuticals	FP-025	MMP 12 inhibitor	Oral	Ph2/3, ended Feb 2022
Edesa Biotech	EB05	Anti-toll-like receptor 4 MAb	IV	Ph3 portion of ph2/3 study 25% enrolled as of Feb 2022
Sorrento Therapeutics	Abivertinib (AC0010)	BTK and EGFR inhibitor	Oral	Ph2/3 trial cleared Mar 2022
Pfizer	Zimlovisertib (PF-06650833)	Irak4 inhibitor	Oral	Ph2 ends Mar 2022*
Atriva Therapeutics	Zapnometinib (ATR-002)	MAPK inhibitor	Oral	Ph2 Respire ends Apr 2022
Humanigen	Lenzilumab	Anti-GM-CSF MAb	IV	Ph2 Activ 5/Bet-B completes Jun 2022*
Danicopan (ALXN2040)	Astrazeneca	Complement factor D inhibitor	Oral	Ph2 Activ 5/Bet-C completes Oct 2022*

**Investigator-sponsored study. Source: Evaluate Pharma & clinicaltrials.gov.*

The table in this story has been updated to include the Activ 5 NIH studies.