Evaluate Vantage

August 25, 2021

Whistleblower is the next problem for Cassava

Jacob Plieth

Speculative biotech plays don't come much flakier than Cassava, a former penny stock that was catapulted to stardom and a $4.7bn valuation on the back of a wave of investor enthusiasm over Alzheimer's disease. Now the company, which fell 24% in July on open-label data with simufilam, faces the problem of a citizen's petition claiming serious misconduct and asking the FDA to halt simufilam's two ongoing clinical trials. The basis for this request, made by the law firm Labaton Sucharow on behalf of a whistleblower, is that Cassava's claim that simufilam blocks amyloid-beta's toxic signalling by restoring the normal shape of filamin A is bogus. "No other lab has [connected] filamin A to Alzheimer's disease," the petition claims, alleging that Western blots going back 15 years, some appearing with very sharp edges, had been manipulated and "pieced together from multiple sources". This morning, with shares off 20%, Cassava called the claims "false and misleading", saying Western blot bands were "supposed to look sharp", and that "proteins can and do stick to the side of a lane and migrate that way". 12-month readout of uncontrolled simufilam data are expected soon, and the two studies are continuing for now.

Simufilam's active clinical trials			
Study	**Design**	**Primary endpoint(s)**	**Data**
NCT04388254	200 mild-to-moderate Alzheimer's patients, placebo	Safety, chg in biomarkers, chg in Adas-Cog11 at <12mth (open-label) & 12-18mth (blinded randomised withdrawal)	Open-label data in 50 patients showed mean 3-point Adas-Cog11 improvement
Rethink-Alz (ph3)	750 mild-to-moderate Alzheimer's patients, vs placebo	52wk chg in Adas-Cog12 & ADCS-ADL	Completion Oct 2023
Source: clinicaltrials.gov.			