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# Bionomics BNC210 Fails Second Phase II Trial (Agitation)

Bionomics says its 40-patient, phase II trial of BNC210 for agitation “did not differentiate from placebo on the primary and secondary efficacy end points”.

Last year, Bionomics fell as much as 69 percent to 15.5 cents on news that BNC210 failed to meet its primary endpoint in a 193-patient trial for post-traumatic stress disorder (PTSD) (BD: Oct 2, 2018).

Today, the company said the top-line results of the BNC210 exploratory trial for agitation in elderly patients in a hospital setting “indicated that BNC210 treatment did not differentiate from placebo on the primary and secondary efficacy end points”.

Bionomics said that comparison of mean peak daily Pittsburgh agitation scale scores, or observations of aberrant vocalization, motor agitation, aggressiveness and resisting care, “showed a gradual improvement for both BNC210 and placebo over the five-day treatment period, but without evidence of a treatment effect”.

The company said that the phase II study was designed to assess the therapeutic potential of BNC210 to treat agitation in hospitalized elderly patients as a separate indication and to evaluate safety of BNC210 in the elderly patient population.

Bionomics said that the safety of BNC210 was confirmed.

Bionomics consultant chief medical officer Prof Paul Rolan said that the trial results “do not support further development of BNC210 for treatment of agitation, [but] given BNC210’s consistent safety profile and the demonstration by pharmaco-metric exposure-response modelling of its potential to treat post-traumatic stress disorder, we remain confident in pursuing PTSD, provided that we can achieve the blood exposure levels predicted by the modelling analysis“.

The company said that to build the case for BNC210, it would invest $300,000 in a single ascending dose study in healthy volunteers to show that BNC210 blood levels necessary to meet the primary endpoints for effectiveness in treating PTSD in a further trial, were achievable using the solid dose formulation, with results expected about October.

Bionomics executive chairman Dr Errol De Souza said that if the solid dose formulation study confirmed that the required blood levels were achievable, and the US Food and Drug Administration guidance supported a second phase II trial of BNC210 in PTSD, “then Bionomics intends to proceed with the further formulation development and preparation for a second phase II trial”.

“We believe that, a second trial of BNC210 in PTSD will be the best option available to Bionomics to rebuild shareholder value,” Dr De Souza said.

“However, it is clear that we will require funding beyond our current resources to do so,” Dr De Souza said.

Dr De Souza said the company had “expressions of interest from third parties to provide funding for the trial” and would engage with shareholders, partners and others.

Bionomics fell as much as 2.2 cents or 39.3 percent to 3.4 cents, before closing down 1.9 cents of 33.9 percent at 3.7 cents with 42.8 million shares traded.

Biotech Daily calculates that Bionomics has a market capitalization of $20.15 million, with $22.1 million in cash at March 31, 2019, and outstanding loans of $18.1 million.