Biotech Daily

Tuesday October 2, 2018

Daily news on ASX-listed biotechnology companies

Bionomics Falls 69% As 'BNC210 Fails PTSD Primary Endpoints'

Bionomics fell 69 percent when its 193-patient, phase II trial of anti-anxiety drug BNC210 in adults with post-traumatic stress disorder (PTSD), failed to meet its primary endpoint.

Bionomics said the trial "did not meet [the] primary endpoint of decrease in PTSD symptoms as measured by CAPS-5 at 12 weeks" (BD: Jun 30, 2016).

The company said the primary endpoint was the clinician-administered PTSD scale for the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5), or CAPS-5.

Bionomics said that "evidence of anti-depressant effects and anti-anxiety activity [was] observed in the CAPS-5 symptom clusters [and] BNC210 treatment was safe and well-tolerated".

Bionomics chief executive officer Dr Deborah Rathjen told a teleconference that the trial produced "positive clinical trial data" and BNC210 was active after a single dose.

Dr Rathjen said that all work on BNC210 would cease, except the current trial for agitation, with results expected by April 2019.

In May, Bionomics said it had recruited the first of up-to 40 patients for its randomized, double-blind phase II trial of BN210 for geriatric agitation (BD: May 23, 2018).

"Unfortunately, we haven't been able to deliver the results we hoped for … and we are deeply disappointed," Dr Rathjen told the teleconference.

Dr Rathjen said the detailed results showed evidence of anti-anxiety effects and a positive safety profile, but the company would stop all other work on BNC210.

Bionomics chief medical officer Prof Paul Rolan said the trial compared three doses of BNC210 (150mg, 300mg, 600mg and placebo) taken twice daily for 12 weeks, with no significant difference between groups except for some trends in the highest dose group.

University of California San Diego psychiatry professor Prof Murray Stein told the teleconference that “although the results were negative for PTSD, BNC210 may have potential for some of the symptoms of PTSD”.

In June 2009, Bionomics said it had begun a 28-patient, phase I trial of anti-anxiety drug BNC210 at the Royal Adelaide Hospital evaluating the safety, tolerability and the pharmacokinetics of BNC210 and in October reported BNC210 was safe, well-tolerated and had “no clinically significant adverse events” (BD: Jun 25, Oct 27, 2009).

Bionomics said at that time that the preclinical profile of BNC210 indicated it was fast-acting and lacked the side-effects seen with current anxiety treatments with the same or greater therapeutic benefit.

In 2011, the company said that two phase Ib trials of BNC210 demonstrated efficacy with reduced sedation and intellectual impairment (BD: Mar 30, 2011).

In 2012, Bionomics said it had licenced BNC210 to the Cambridge, Massachusetts-based Ironwood Pharmaceuticals in a potential $US345 million deal, with a $US3 million (then $A2.9 million) upfront fee but potentially $US345 million in upfront and milestone payments and research funding, as well as royalties on sales of products incorporating BNC210 and other related compounds, with Ironwood responsible for development and commercialization of all products incorporating BNC210 or other licenced compounds, including clinical trials (BD: Jan 22, 2012).

In 2014, Bionomics said it had taken back anti-anxiety drug BNC210 from Ironwood saying the two companies “mutually agreed to terminate this arrangement” but Ironwood would retain a royalty interest in BNC210 (BD: Nov 11, 2014).

Last night on the US OTC market, Bionomics was up 58.4 percent to 61 US cents (84.5 Australian cents), with 227,832 shares traded.

Today, Bionomics fell as much as 34.5 cents or 69.0 percent to 15.5 cents before closing down 33 cents or 66 percent to 17 cents with 38.2 million shares traded.