Biotech Daily

Tuesday April 7, 2020

Daily news on ASX-listed biotechnology companies

Zelira: Marijuana ZLT-101 'Effective For Insomnia'

Zelira says its 23-patient, phase Ib/IIa trial of marijuana-derived ZLT-101 has shown safety and statistical significance for reduction of chronic insomnia.

Zelira said that the randomised, double-blind, cross-over trial treated patients for 14 nights with ZTL-101 and 14 nights of placebo, separated by a one-week washout period at the University of Western Australia Centre for Sleep Science.

The company said that the primary endpoint of insomnia severity index (ISI) showed an average 26 percent reduction for the low dose (0.5ml of 11.5mg cannabinoids) and high dose (1.0ml of 11.5mg cannabinoids) ZLT-101 groups compared to placebo, with the high dose achieving a 36 percent reduction.

Zelira said that the placebo ISI score was 18.0 compared to the low dose drug score of 14.8 ($p < 0.05$) and high dose ISI score of 11.1 ($p < 0.001$).

The company said that for the secondary endpoint of total sleep time, the low dose group exceeded placebo by 28 minutes ($p < 0.05$) and the high dose ZLT-101 group by 42 minutes ($p < 0.001$).

Zelira said that the decrease in wake time after sleep onset showed a non-significant reduction of 9,52 minutes comparing low dose to placebo, but a significant 12.31 minutes for the high dose group ($p < 0.05$).

Zelira chief executive officer Dr Richard Hopkins told Biotech Daily that there was a clear dose response relationship and "a number of quality-of-life measures all pointed in the right direction".

Dr Hopkins said that patients receiving ZLT-101 compared to placebo generally felt more rested on waking with the high dose group reporting a significant difference compared to placebo ($p < 0.001$) while the low dose was not significant.

Dr Hopkins said that Zelira intended to market ZLT-101 in Australia by October 2020 and it could begin steps to licence the product in the US from today.

Dr Hopkins said the company would maintain its focus on insomnia and was currently designing a phase IIb trial extending the time period for patients receiving ZLT-101, to be followed by a phase III trial.

Zelira said that ZTL-101 was safe, with participants reporting “only minor adverse events” including dry mouth and headache with 96 percent of symptoms resolving by the next morning.

The company said that patients “tolerated the maximal dose well”.

University of Western Australia Centre for Sleep Science director and principal investigator Prof Peter Eastwood said the study was “the most rigorous clinical trial ever undertaken to assess the therapeutic potential of medicinal cannabis to treat the symptoms of chronic insomnia”.

“The fact that ZLT-101 treatment achieved statistically significant, dose responsive improvements across a broad range of key insomnia indices is impressive, particularly given the relatively short two-week dosing window,” Prof Eastwood said.

“The significant improvement in subjective sleep quality and feelings of waking up rested as reported by participants was particularly notable,” Prof Eastwood said.

“Positive patient experiences with minimal side-effects are critical to the success of any insomnia drug and highlights the potential for ZTL-101 to address a key area of unmet need,” Prof Eastwood said. “It is likely that further improvements in efficacy could be achieved by dosing over a longer period and potentially at higher doses.”

“Taken together, these results are comparable to other approved insomnia therapies at a similar stage of development and suggests that ZLT-101 can be developed as a novel treatment for chronic insomnia,” Prof Eastwood said.

Zelira was up 0.8 cents or 22.2 percent to 4.4 cents with 4.7 million shares traded.