EFFICACY OF ZELIRA'S MEDICINAL CANNABIS FORMULATION FOR TREATING CHRONIC INSOMNIA

FINAL REPORT FOR PHASE 1A/2B CLINICAL TRIAL

ASX: ZLD

OTCQB: ZLDAF

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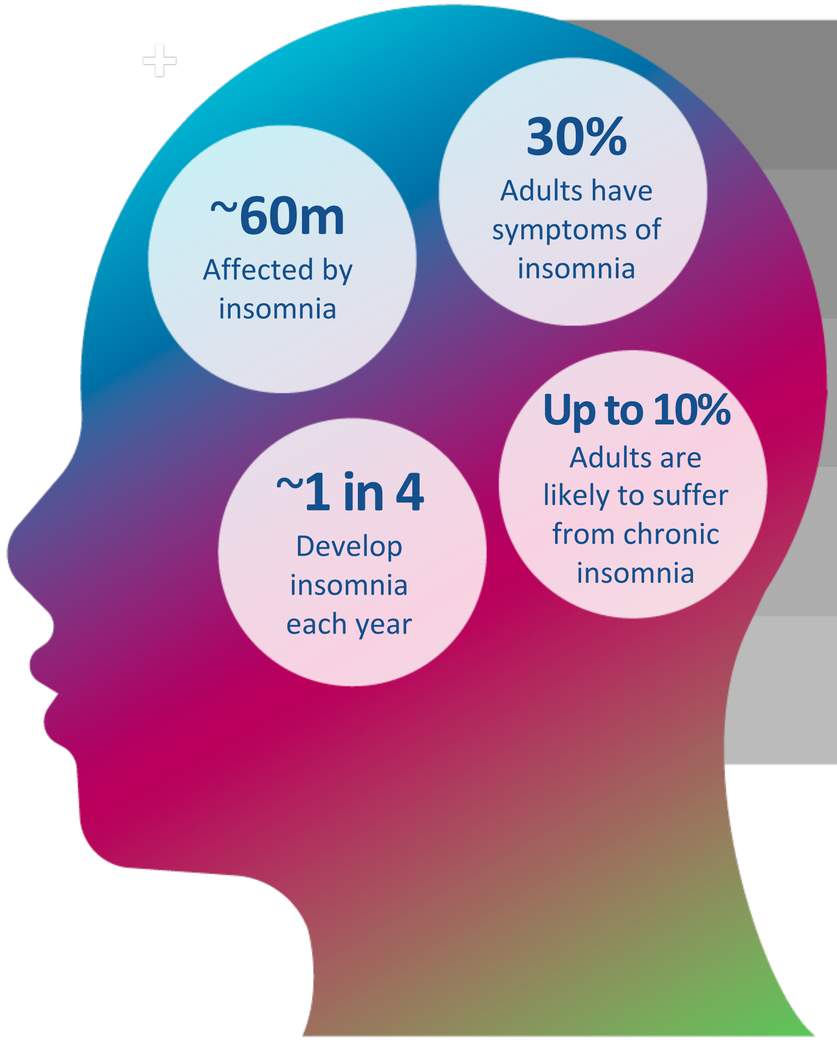
KEY INSOMNIA STATS-USA MARKET

Insomnia is the most common sleep disorder in America



83% Of people who suffer from depression also experience symptoms of insomnia.

Nearly 50% Of adults > 60 suffer from symptoms of insomnia.

30% Of opioid overdoses involve medications commonly prescribed for insomnia.

$63bn Economic loss to the US economy/yr due to insomnia

$4bn Expected value of the US insomnia market by 2021

UNMET NEED

Short Term Side-Effects of Approved Insomnia Medications

- ‘Next Day’ effects: groggy, dizzy, tired, headaches, constipation and dry mouth

Long Terms Side-Effects of Approved Insomnia Medications

- Dependence and Tolerance
- Withdrawal symptoms
- Rebound insomnia
- Increased risk of depression, cancer, mood disorders, suicides, serious infections

Commercial opportunity exists for new insomnia therapies that offer improved efficacy and/or improved safety and tolerability

ZELIRA: INSOMNIA PHASE 1A/2B TRIAL

A Study to Evaluate the Efficacy of Sublingual Cannabinoid Based Medicine Extract (ZTL-101) Compared with Placebo for the Treatment of Sleep Disorders Due to Insomnia

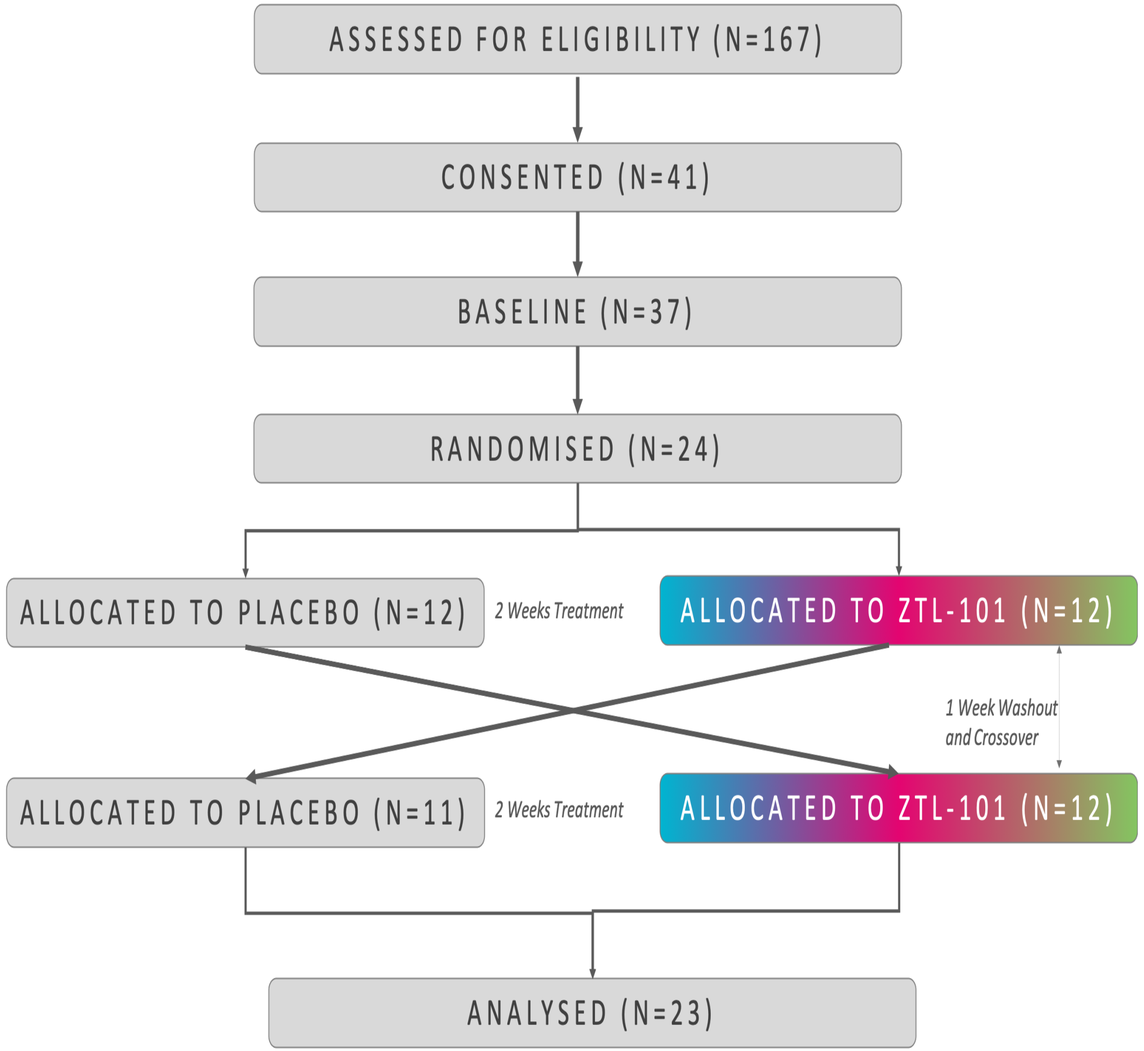
Investigational Team: PI - Prof Peter Eastwood, Clinical Prof David Hillman, Ass Prof Nigel McArdle, Dr Melissa Ree, Dr Jennifer Walsh

Study design: Randomised double-blind, placebo-controlled, crossover

ANZCTR: ACTRN12618000078257

Primary Outcomes:	Secondary Outcomes:
• To evaluate safety and tolerability of increasing doses of the sublingual cannabinoid extract ZTL-101. • To evaluate the efficacy of the sublingual cannabinoid extract ZTL-101 containing THC for improving insomnia symptoms in people with chronic insomnia.	• To evaluate the efficacy of ZTL-101 as compared to placebo for improving objective and subjective sleep quantity and quality in people with insomnia. • To evaluate quality of life improvements in people with insomnia when using ZTL-101 as compared with placebo.

ZELIRA: INSOMNIA PHASE 1A/2B TRIAL DESIGN



Inclusion criteria:

- Chronic insomnia

  (self-reported difficulty initiating and/or maintaining sleep on three or more nights per week for at least 3 months)

- ISI score >10

Exclusion criteria:

- Sleep apnea
- Severe depression, anxiety or stress

Formulation: THC, CBD, CBN

Dosing:

- Sublingual
- Nightly 1 hour before bed for 2 weeks
- Low dose ZTL-101 = 11.5mg total cannabinoids
- High dose ZTL-101 = 23mg total cannabinoids

PATIENT COMMENTS*

Person	Placebo	ZTL-101
	*“Has zero effect on any insomnia.”*	**“Fell asleep and did not wake up in middle of night…more than in past 22 years.”**
	*“Even with double doses for this arm, still not sleeping.”*	**“I haven't slept this well in a very long time.”**
	*“Stayed awake for hours trying to sleep most nights, same as prior to taking any medication…”*	**“Slept well, night passed quickly.”**

** Responses from participants after spending night in sleep lab following 2 weeks of treatment course with either placebo or ZTL-101*

ZTL-101 MET PRIMARY AND SECONDARY ENDPOINTS

Primary Endpoints

SAFE

- No serious adverse events
- Adverse events mild and transient
- Maximal dose well tolerated

EFFICACIOUS

- 36% reduction in Insomnia Severity Index (ISI)
- Treatment was dose responsive
- High dose patients became subclinical to insomnia
- Statistically significant reduction in ISI scores at all doses

Secondary Endpoints

Improved Objective and Subjective Measures of Insomnia

Statistically significant improvement in:

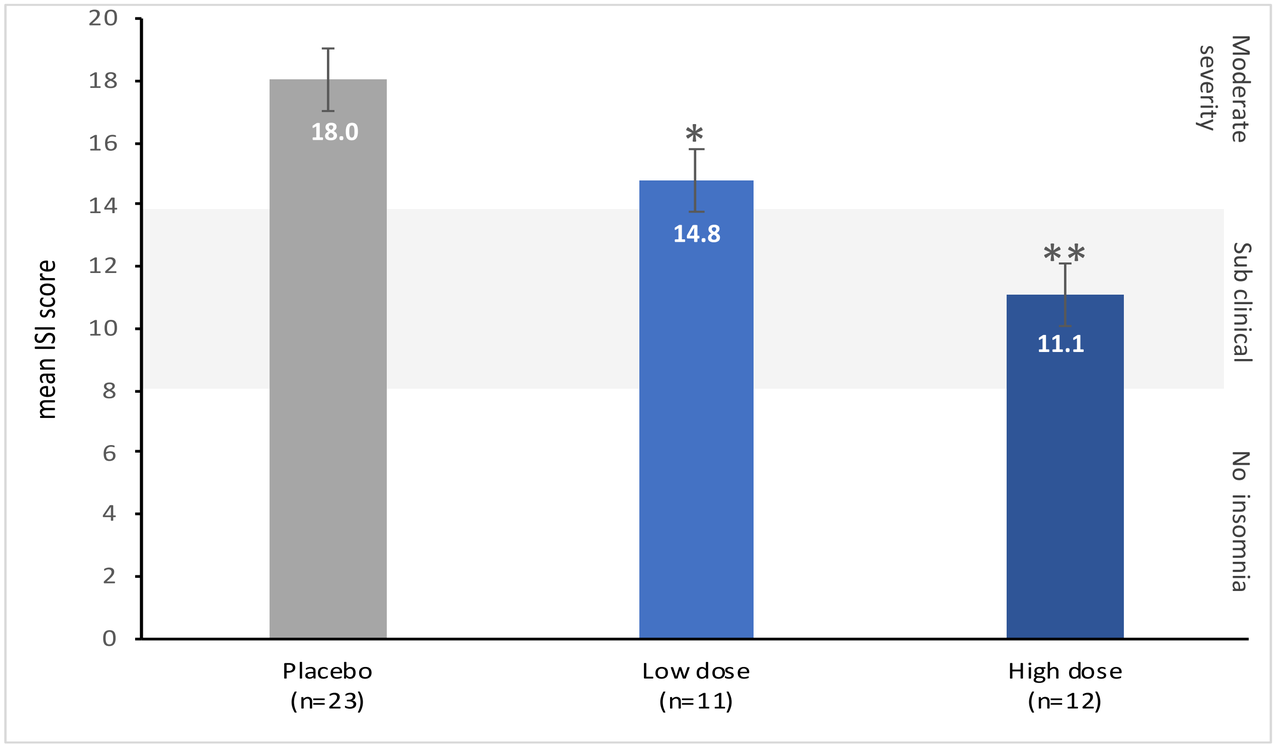
- Time spent asleep
- Time taken to return to sleep after waking
- Sleep quality
- Feeling rested

Improved Quality of Life

Statistically significant:

- Reduction in levels of fatigue
- Improvement in functioning

ZTL-101 IMPROVES INSOMNIA SEVERITY INDEX (ISI) SCORES



- ISI scores significantly improved following ZTL-101 treatment vs placebo at all doses.
- High dose of ZTL-101 achieved a **36%** reduction in ISI scores.
- High dose of ZTL-101 saw people downgraded from ’Moderate Severity’ to ‘Sub Clinical’ clinical insomnia.

Statistical significance calculated using adjusted means for low dose subgroup (ZTL-101 vs placebo-18.7 ISI) and high dose subgroup (ZTL-101 vs placebo- 17.4 ISI). *p<0.05, **p<0.005.

ZTL-101 IMPROVED OBJECTIVE MEASURES OF SLEEP (ACTIGRAPHY)

ZLT-101 vs Placebo	Total Sleep Time (min)	Sleep Efficiency (%)	Wake After Sleep Onset (min)	Sleep Onset Latency (min)
Low dose (n=11)	↑28*	↑2.61*	↓9.52	↓0.25
High dose (n=12)	↑42**	↑3.57**	↓12.31*	↓1.19*
Average	**↑33****	**↑2.89****	**↓10.17***	**↓0.41**

ZTL-101 significantly:

- Increased the time people spent asleep (TST more than 30 mins and SE by 3%)
- Decreased the amount of time people spend awake during the night (WASO by less than 10 mins)
- Responses improved with increasing dose

Definitions:
Total Sleep Time (TST): Total amount of sleep time recorded. **Sleep Efficiency (SE):** Sum of time spent asleep divided by the total time in bed. **Wake After Sleep Onset (WASO):** Amount of time spent awake after sleep onset. **Sleep Onset Latency (SOL):** Duration of time from 'lights out' until patient falls asleep.

Statistical significance calculated using adjusted means for ZTL-101 vs placebo. * $p \leq 0.05$, ** $p \leq 0.001$

ZTL-101 IMPROVED SUBJECTIVE MEASURES OF SLEEP (PATIENT SLEEP DIARIES)

ZLT-101 vs Placebo	Total Sleep Time (min)	Quality of Sleep (score)	Rested on Waking (score)	Sleep Onset Latency (min)
Low dose (n=11)	↑60*	↑0.53*	↑0.26	↓10.2
High dose (n=12)	↑77**	↑0.98**	↑0.75**	↓10.5
Average	**↑65****	**↑0.74****	**↑0.51***	**↓8.5***

ZTL-101 significantly:

- Increased the time people thought they spent asleep
- Improved the quality of sleep people felt they had
- Improved how rested they felt on waking
- Responses improved with increasing dose

Statistical significance calculated using adjusted means for ZTL-101 vs placebo. * $p \leq 0.05$, ** $p \leq 0.001$

ZTL-101 IMPROVED PEOPLE'S QUALITY OF LIFE MEASURED USING SUBJECTIVE QUESTIONNAIRES

ZLT-101 vs Placebo	Multidimensional Fatigue Inventory			Work and Social Adjustment Scale	
	General Fatigue[1]	Mental Fatigue[1]	Total Fatigue[1]	Home Management[2]	Total WSAS[2]
Low dose (n=11)	↓1.68*	↓2.0*	↓4.54	↓0.41	↓1.8
High dose (n=12)	↓1.38	↓1.0	↓3.63	↓0.63*	↓2.13
Average	**↓1.57****	**↓1.37***	**↓3.71****	**↓0.6***	**↓2.2***

ZTL-101 significantly:

- Reduced people's total fatigue – particularly mental fatigue and stress[3] (data not shown)
- Improved the ability of people to function – particularly the ability to manage the home

Questionnaires: 1. Multidimensional Fatigue Inventory, 2. Work and Social Adjustment Scale (WSAS), 3. DASS – Stress. Statistical significance calculated using adjusted means for ZTL-101 vs placebo. * $p \leq 0.05$, ** $p \leq 0.001$

ZTL-101 COMPARABLE TO CURRENT SLEEP MEDICATIONS

Criteria	ZTL-101	Temazepam (Temtabs®) Aspen	Zolpidem (Stilnox®/Ambian®) Sanofi	Suvorexant (Belsomra®) Merck	Melatonin
Rapid Sleep Onset	+/-	✓	✓	X	X
Improved Sleep Maintenance	✓	+/-	X	✓	X
Increase Total Sleep	✓	✓	✓	✓	X
Improve ‘Quality of Sleep’	✓	✓	✓	X	X
Feel Rested Upon Waking	✓				
No Serious Side-Effects	✓	+/-	+/-	+/-	X
Maintain effect long-term	TBD	X	X	✓	X
No potential for addiction	TBD	X	X	✓	X

SUMMARY FOR ZTL-101

- **First** clinically validated medicinal cannabis drug targeting chronic insomnia
- **Phase 1b/2b** clinical trial successfully achieved all primary and secondary endpoints
- **ZTL-101:** safe and tolerable
- **ZLT-101** is efficacious: Patients slept longer, slept sooner after waking, spent more time asleep and reported feeling rested, less stressed and fatigued the next day
- **ZTL-101** addresses unmet need for insomnia medications that improve quality of life
- **On-track** to launch into global markets by Q3 2020

NEXT STEPS: LAUNCH, LEARN & DEVELOP