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## **SIGNIFICANT ANTI-CANCER EFFECT OBSERVED IN PRE-CLINICAL STUDIES**

### **Highlights**

- **Zelda reports positive results of its initial proof of concept study into the anti-cancer effects of its THC-rich medical cannabis formulation**
- **Conducted by world leading cannabis cancer researchers at Complutense University of Madrid, the results show that Zelda's formulation of THC-rich oil is:**
  - **Significantly more potent at reducing tumour growth than pure THC**
  - **Equally as potent as Lapatanib in reducing tumour growth**
- **Positive results provide support for Zelda to continue its programme of study evaluating its THC-rich medical cannabis formulations as anti-cancer therapeutics**

The Board of **Zelda Therapeutics Ltd (ASX: ZLD, Zelda or the Company)** is pleased to announce the positive results of its initial proof of concept study into the anti-cancer effects of its THC-rich medical cannabis formulation. The study was conducted on behalf of Zelda by world leading cannabis cancer researchers at Complutense University of Madrid, led by Professor Cristina Sánchez and Professor Manuel Guzmán.

Specifically, this initial study compared the anti-tumour responses of pure tetrahydrocannabinol (THC) versus the Zelda Therapeutics formulation of THC-rich oil and at the same time compare the potency against a standard chemotherapy drug, Lapatanib which is a tyrosine-kinase inhibitor of HER2 and EGFR, both receptors known to play an important role in breast cancer.

**The study showed that the Zelda Therapeutics' formulation of THC-rich oil was significantly more potent at reducing tumour growth than pure THC and more importantly, was as potent as Lapatanib in reducing tumour growth.**

The study was carried out in immune-deficient mice hosting xenografts (tissue grafts) of human breast cancer, HER2+ adenocarcinoma. Treatment was delivered orally and tumour volume was measured daily.

The positive results provide support to continue the study of Zelda formulations as anti-cancer therapeutics in their own right or in combination with current chemotherapy and radiotherapy regimes. A series of follow-on studies are in progress that will include mechanism of action studies, testing other formulations of Zelda cannabinoids and also testing against other cancer cell lines including HER2+ cells resistant to HER2-targetted treatments and triple-negative breast cancer cells.

Professors Sánchez and Guzmán are acknowledged as world leaders in studying the anti-cancer effects of cannabinoids and have published pioneering papers in prestigious scientific journals detailing specific mechanisms of action of cannabinoids on certain cell pathways. Both researchers sit on the Zelda Medical Advisory Board and provide significant guidance in terms of our pre-clinical research focus.

The study forms part of a multi-year work programme, funded by Zelda, at the Complutense University focused specifically on gaining a better understanding of the efficacy of certain whole-plant extracts known to have biological activity in humans through the activities of our partner *Aunt Zelda's* in California.

Our focus in this research programme is to generate data packs in a form typically expected by the bio-pharmaceutical industry. The ultimate aim is to licence this intellectual property to a major group better resourced to progress into formal human clinical trials in the area of cancer therapy. As per the Company's business model, Zelda will benefit through structuring deals comprised of up-front payments, milestones and royalties from these licensees.

**Commenting on the study results, Executive Chairman Harry Karelis stated:**

"We are very excited by the data generated in this preliminary study examining our cannabis extracts in well validated models of human breast cancer. This provides a solid foundation to continue to examine the anti-cancer effects of whole-plant cannabis extracts particularly as a combination therapy for cancer sufferers."

"Future studies will examine the potential to significantly increase the anti-cancer effect of traditional chemotherapy drugs and is an exciting opportunity that can not only improve a patient's quality of life but also potentially extend life expectancy. There is a long way to go before this approach reaches formal human clinical trials but importantly, this data supports the anecdotal experiences already seen in patients in California."

**Professor Cristina Sánchez stated:**

"These preliminary results are very exciting and strongly point in favour of using whole-plant extracts over single cannabinoid molecules. We are in the process of designing and conducting a series of follow-on experiments in coming months which will continue to add to our body of knowledge in this field."

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**About Zelda Therapeutics ([www.zeldatherapeutics.com](http://www.zeldatherapeutics.com))**

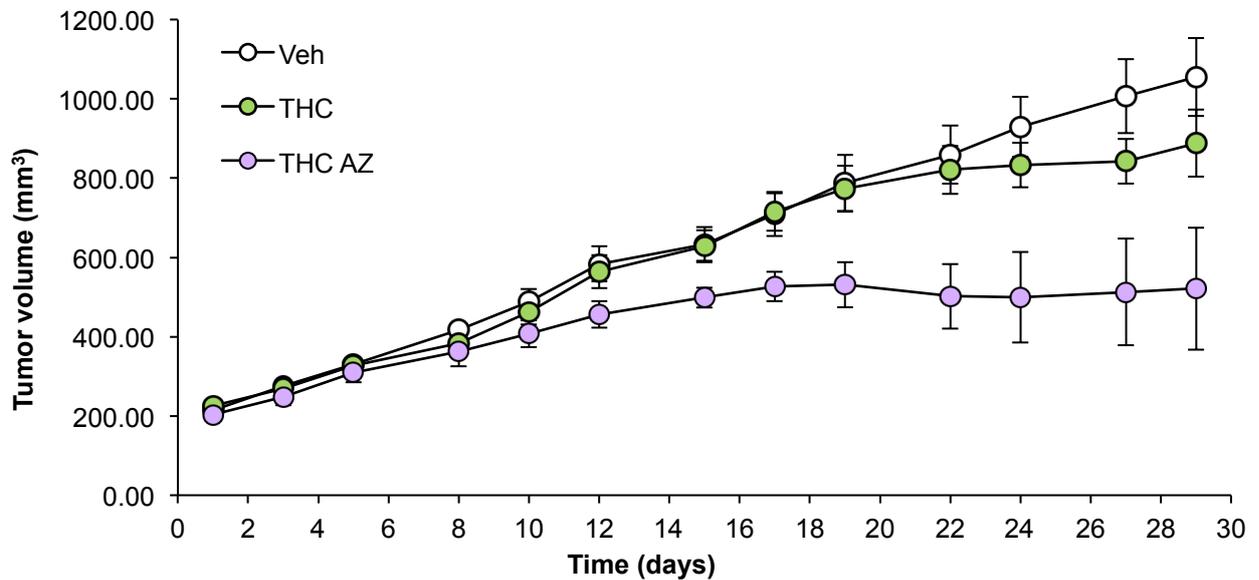
Zelda Therapeutics ("Zelda") is an Australian-based bio-pharmaceutical company that has secured exclusive, global access to an extensive set of human data related to medicinal cannabis based formulations and treatment protocols. This human data has been generated over several years by a California-based group (*Aunt Zelda's*) that has a very high profile within the USA and a growing international profile based upon its deep knowledge of the scientific rationale for certain cannabis-based formulations and protocols to treat a variety of medical conditions.

Zelda has been granted a worldwide, exclusive and perpetual licence to this data, related systems, formulations and treatment protocols. Zelda will use this information to design a series of human clinical trials that have a high probability of success given the existing patient data and experiences it has access to.

In addition, Zelda has partnered with the world's leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct certain pre-clinical work testing cannabis-based formulations known to have an effect in humans in order to generate data packs in a form expected by regulators and the pharmaceutical industry.

## RESULTS

### Comparison of Zelda formulation to pure THC

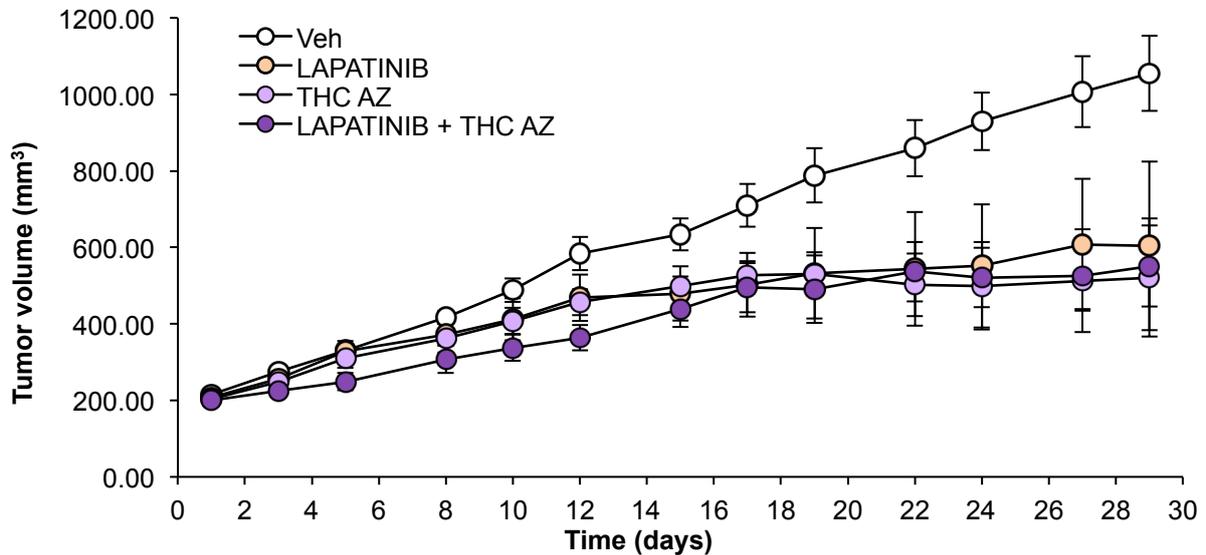


#### CONCLUSIONS

- The Zelda (THC AZ) THC-rich cannabis oil was significantly more potent at reducing tumor growth than pure THC

- It is important to note that the total amount of THC received by the animals was the same in both THC and Zelda (THC-AZ) groups. The difference in response is therefore due to the accompanying compounds (either to their own antitumor properties and/or to synergic effects with THC) otherwise referred to as the "entourage effect"

### Comparison of Zelda formulation to standard care



#### CONCLUSIONS

- Zelda THC-rich oil is as potent as Lapatinib in reducing tumor growth

- The combination of Zelda THC-rich oil with Lapatinib does not increase the antitumor responses of either Lapatinib or the extract alone.

NOTE: "Veh" refers to the control group of animals who had no treatment of their tumours