



22 August 2022

## **Creso Pharma's wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. secures key updates to its Clinical Trial Authorisation**

### **Highlights:**

- **Amendment to Clinical Trial Authorisation ("CTA") secured from Health Canada marks penultimate step towards commencement of clinical trial**
- **Halucenex's phase II clinical trial will test the efficacy of psilocybin on symptoms associated with treatment resistant Post Traumatic Stress Disorder (PTSD)**
- **Recent amendment granted by Health Canada will allow patient cohorts using other medication associated with managing PTSD to participate in the trial, if selected by Halucenex**
- **Allows Halucenex to generate additional data around psilocybin use alongside other pharmacological treatments**
- **Final Ethics Review Board submissions made with outcome expected imminently**
- **Subject to Ethics approval, first dosages under clinical trial settings expected to be administered in or around September 2022, utilizing Lucenex branded 10mg and 25mg psilocybin finished product formulation**
- **Trial has the potential to unlock large market opportunity for Creso Pharma and access to the PTSD therapeutics sector which is expected to grow to US\$10.5Bn in value by 2025<sup>i</sup>**

**Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company')** is pleased to advise that wholly-owned, Canadian based psychedelics company, Halucenex Life Sciences Inc. ("Halucenex") has secured an amendment to its Clinical Trial Authorisation ("CTA") from Health Canada. This amendment is a step closer towards the commencement of Halucenex's planned phase II clinical trial to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD).

Following a large number of enquiries regarding participation in the trial and ongoing assessment, Halucenex sought an amendment to its CTA to allow patient cohorts currently using Selective Serotonin Reuptake Inhibitors (SSRIs) and not require potential patients to stop using prescribed medications for a week prior to the potential Phase II trials' commencement.

This adjustment has since been granted by Health Canada and will provide a number of benefits, including a broadened patient scope, as well as data on how psilocybin interacts when used in combination with other medication utilised by PTSD sufferers.

The Company advises that final submissions have been made to the Ethics Review Board and the outcome is expected shortly. Upon receipt of ethics approval, Halucenex expects to be in a position to begin first dose administration under clinical trial protocols in or around September 2022.

Halucenex's phase II clinical trial will provide the Company with potential access to a large and rapidly growing market. The PTSD therapeutics sector is expected to grow to US\$10.5Bn in value by 2025, unlocking a major opportunity for Halucenex.



The Company continues to engage with its Ethics Board and will provide updates to shareholders as further developments materialise.

**Commentary:**

**CEO and Managing Director William Lay said:** *"To have secured this amendment from Health Canada is a major step forward for Creso Pharma, Halucenex and patients managing symptoms associated with PTSD while using other medication."*

*"This clinical trial has the potential to unlock a new and natural alternative to current pharmacological treatments used by PTSD sufferers, while unlocking a new market for the Company. We continue to liaise with our Ethics Review Board, potential patient groups and all clinical trial personnel and expect to administer first dosages to patients in or around September 2022 (subject to ethics review approval). I look forward to providing additional details on developments in due course."*

**-Ends-**

**Authority and Contact Details**

This announcement has been authorised for release by the Disclosure Committee of the Board of Directors of Creso Pharma Limited.

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**About Creso Pharma**

Creso Pharma Limited (ASX:CPH) brings the best of cannabis to better the lives of people and animals. It brings pharmaceutical expertise and methodological rigor to the cannabis world and strives for the highest quality in its products. It develops cannabis and hemp derived therapeutic, nutraceutical, and life style products with wide patient and consumer reach for human and animal health.

Creso Pharma uses GMP (Good Manufacturing Practice) development and manufacturing standards for its products as a reference of quality excellence with initial product registrations in Switzerland. It has worldwide rights for a number of unique and proprietary innovative delivery technologies which enhance the bioavailability and absorption of cannabinoids. To learn more please visit: [www.cresopharma.com](http://www.cresopharma.com)

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**Forward Looking statements**

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The cautionary statements qualify all forward-looking statements attributable to Creso and persons acting on its behalf. Unless otherwise stated, all forward-looking statements speak only as of the date of this announcement and Creso has no obligation to up-date such statements, except to the extent required by applicable laws.

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<sup>1</sup> Credence Research PTSD Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026