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Wholly owned subsidiary, Halucenex Life Sciences Inc. to pursue Australian market entry following landmark TGA decision

Highlights:

- **Therapeutic Goods Administration (TGA) has approved medicines containing psilocybin and MDMA for prescription by specifically authorised psychiatrists for the treatment of certain medical conditions from 1 July 2023**
- **Medical conditions listed by the TGA include treatment resistant Post Traumatic Stress Disorder (PTSD)**
- **Halucenex is currently advancing a phase II clinical trial to test the efficacy of psilocybin on treatment resistant PTSD which is expected to complete in H1 2023**
- **As the new regulations come into effect close to the expected completion date of the trial, Creso Pharma intends to explore opportunities for registration of its synthetic psilocybin in Australia**
- **Halucenex is recognised as a licensed psilocybin supplier under Health Canada's Special Access Program and is well advanced in psychedelic assisted therapy R&D**
- **Real world data generated from the ongoing trial may form the basis of the Company's Australian market strategy**

Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to advise that wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. ("Halucenex") is exploring opportunities to register its synthetic psilocybin formulation for the Australian market following recent regulatory changes.

The Australian medical regulator, the Therapeutic Goods Administration's (TGA) recently announced that the medical use of MDMA and psilocybin respectively will be rescheduled from Schedule 9 (prohibited substances) to Schedule 8 (controlled medicines) which will allow for both substances to be prescribed by specifically authorised psychiatrists for the treatment of certain health conditions, including treatment resistant Post Traumatic Stress Disorder (PTSD) from 1 July 2023[i].

Halucenex is currently undertaking a Phase II clinical trial which will test the efficacy of psilocybin on treatment resistant PTSD (refer ASX announcement: 7 December 2022).

The Company has recruited 20 patients from the single–arm, open-lab trial that all suffer from the condition, as well as other mental illnesses such as (but not limited to) anxiety, suicidal thoughts, ADHD, depression and anger (refer ASX announcement: 6 October 2022).

The Company is confident that the data generated from this trial will provide a strong foundation for the registration of its Lucenex branded synthetic psilocybin product, as a potential treatment route in Canada and Australia, pending further regulatory requirements. Halucenex is already a Licensed Psilocybin Supplier under Health Canada's Special Access Program.

Creso Pharma will continue work alongside Australian-based research organisations and potential partners to progress these opportunities.

CEO and Managing Director, Mr William Lay said: *"This is a landmark moment for psychedelic therapy in Australia. The TGA's decision provides considerable validation of Halucenex's work to date, and highlights the significant opportunity Creso Pharma has as an early stage pioneer of medical psilocybin.*

"Halucenex's clinical trial is advancing pleasingly. We are confident that data generated from the initiative will provide a much greater insight into how Lucenex can be used as a potential treatment route for debilitating health conditions."

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Authority and Contact Details

This announcement has been authorised for release by the Disclosure Committee 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

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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.

[i] https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists