9 June 2023

Creso Pharma signs Letter of Intent to import licensed MDMA and psilocybin treatments to Australia from Switzerland

Highlights:

- **Letter of Intent (LOI) secured to enter an exclusive commercial relationship with Apotheke Dr. Hysek AG, a leading Swiss pharmaceutical company, for the supply of GMP MDMA and synthetic psilocybin products to the Australian market**
- **Creso, through its wholly owned Australian subsidiary Health House International (HHI), currently holds the necessary import licences for the Australian market and will provide the support infrastructure to import, warehouse and distribute the products throughout Australia – additional applications for import permits to be pursued shortly**
- **Dr. Hysek AG manufactures MDMA and synthetic psilocybin under Pharma GMP conditions and with authorisation by Swiss medicine agency (Swissmedic) and the FOPH (Federal Office of Public Health)**
- **Creso and HHI are establishing connections with a variety of stakeholders in Australia, in alignment with the Therapeutic Goods Administration (TGA) guidance that medicines containing psilocybin and MDMA for prescription by specifically authorised psychiatrists for the treatment of certain medical conditions will be permissible from 1 July 2023**
- **Dr Hysek AG has supplied MDMA and psilocybin in Switzerland under the Swiss limited-use program for psychedelics since 2015**
- **Dr. Hysek AG has been the manufacturer of psychedelics used in several clinical trials**
- **Dr. Hysek has a close collaboration with Dr Matthias Liechti, a professor at University Hospital Basel who works closely with the FOPH, which is responsible for issuing approvals for psychedelics use in Switzerland**
- **The product knowledge and lengthy experience of Drs Hysek and Liechti and the Swiss team of researchers and therapists brings a unique understanding of the needs of patients with specific treatment-resistant mental illnesses**
- **Signed LOI sets out the principal terms and conditions under which the parties intend to enter into a Commercial Agreement for the distribution of Dr. Hysek AG products into the Australian market – commercial agreement anticipated by 31 August 2023**

Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to announce it has signed a Letter of Intent (LOI) with Swiss-based pharmacy Apotheke Dr. Hysek AG, to enter an exclusive commercial partnership for the import and distribution of authorised MDMA and psilocybin products into Australia.

Under the LOI, it is proposed that Creso Pharma will provide the infrastructure to import, warehouse and distribute the products through its wholly-owned subsidiary, Health House International (HHI) which currently holds the necessary import licences for the Australian market. The commercial terms of the partnership have not yet been agreed, however the parties have undertaken to negotiate these in good faith and enter into a detailed Commercial Agreement on or before 31 August 2023. There is

also no certainty a Commercial Agreement will materialise and the financial impact of the LOI is not yet known and will be determined by any such Commercial Agreement. The LOI, whilst binding, may be terminated by either party without cause by giving written notice, and the LOI will expire on 31 August 2023 if no Commercial Agreement is entered into by the parties by that date (unless extended by mutual agreement).

The Agreement follows the February 2023 decision by the Therapeutic Goods Administration (TGA) which stipulated that medicines containing psilocybin and MDMA can be prescribed by specifically authorised psychiatrists for the treatment of certain mental health conditions from 1 July 2023.

Creso Pharma will leverage Health House International to commence the importation process at the appropriate time. HHI currently has two relevant licences in place in line with the TGA guidelines, which include a Wholesale and manufacturer licences, covering Schedule 2, 3, 4 and 8 poisons and a Schedule 9 Licence, which covers MDMA and Psilocybin.

To make any substance imported under the agreement commercially available in Australia, HHI will also apply for an import permit through the Australian Office of Drug Control (Narcotics Control Section), with the clear intent of the exporter involved, medicine intended to be imported and under what pathway of clinical intent.

The Creso-HHI team is discussing with a variety of stakeholders in Australia including GPs, pharmacists and practicing psychiatrists, with a focus on forming alliances with health professionals who wish to enter the sector. HHI also maintains regular and close contact with the Australian regulator, the Therapeutic Goods Administration (TGA) to ensure it continues to operate in line with relevant guidelines.

About Apotheke Dr. Hysek AG:

Located in Biel, Switzerland, Apotheke Dr. Hysek AG is a Good Manufacturing Practice (GMP) certified medication production facility which manufactures MDMA, synthetic psilocybin, and LSD under Pharma GMP conditions and with authorisation by Swiss medicine agency (Swissmedic) and the FOPH.

Founded by Swiss pharmacist Dr Cedric Hysek, the facility employs around 25 people and supplies controlled substances for clinical studies and limited use in patients to universities, physicians, and selected companies. Products are distributed in accordance with Good Distribution Practice (GDP) standards to the relevant license holders.

Dr Hysek also collaborates with Dr Matthias Liechti, a professor at University Hospital Basel. Dr Liechti has been involved with the Swiss limited-use program for psychedelics since its inception in 2015. Dr. Liechti works closely with the Federal Office of Public Health (FOPH), which is responsible for issuing exemption permits for the medical use of psychedelics. He works on drug interactions and consults directly to physicians in this area.

Creso Pharma CEO and Managing Director, Mr William Lay said: *"This Letter of Intent sets out the terms and parameters for the licensed import and distribution of approved MDMA and psilocybin products to Australia, manufactured by one of the world's foremost practitioners in this space.*

"Dr Hysek is undoubtedly a pioneer in the application of MDMA and psilocybin treatments to achieve better patient outcomes, with a product suite that has been developed in close collaboration with Swiss regulators and university researchers.

"The proposed terms of the commercial agreement position Creso and HHI to play a leading role in the expansion of these treatment solutions in Australia, in alignment with the changes set out by the TGA with respect to the prescription of approved MDMA and psilocybin products.

"We look forward to working with all stakeholders over the coming months, including registered health professionals and practicing psychiatrists who have made expressions of interest, to build further on the exciting work already carried out to-date."

Dr Matthias Liechti commented: *"Since 2015, Switzerland has adopted a collaborative approach between federal regulators, university researchers and medical industry professionals to establish an effective framework for the limited-use supply of MDMA and psilocybin products for improved medical outcomes. This LOI provides a potential opportunity to share that knowledge with both the TGA and key stakeholders in the Australian healthcare industry to develop similarly effective programs in the Australian market. As a research partner of the Swiss limited-use program since inception, I have a direct interest in assisting in the efficient and regulated rollout of these medical applications to other jurisdictions and would embrace the opportunity to work closely with the Australian medical industry towards that goal."*

Dr Cedric Hysek said: *"We are pleased to enter into this LOI to establish the framework for a broader commercial agreement between Apotheke Dr. Hysek AG and Creso Pharma through its subsidiary, Health House International. Our products are manufactured and distributed in accordance with the highest GMP standards and the company is now uniquely positioned with an extensive manufacturing history, with long-term product development IP which has been developed in direct consultation with federal Swiss health regulators. With our extensive background in this field of medicine, it's exciting to have the opportunity to collaborate with Creso Pharma and set out the path forward for the growth of the industry in Australia."*

Swiss regulatory framework for limited-use supply of MDMA and psilocybin

Switzerland is known for its very pragmatic approach to the use of psychedelics in clinical trials and in patients. As a result, the country has become a leader in the research and use of psychedelics in psychiatry. Nevertheless, the regulatory hurdles for researchers and patients are still extremely high.

Applications for the limited-use of MDMA and psilocybin products to treat a range of conditions (subject to provision of evidence for the indications) are made via the FOPH. The process typically takes about 3 months from application to approval.

With a congruent medical justification, psychedelics can theoretically be prescribed in Switzerland by any physician with a medical license. Mostly, however, they're prescribed by psychiatrists. The supervision of use can be delegated to psychologists or other health professionals under the responsibility of the license holder. Currently, there are about 50 physicians who prescribe and a patient base of approximately 300. It is expected the number of patients will increase to about 500-600 during 2023.

MDMA is typically prescribed for PTSD and psilocybin for depression, anxiety and alcohol use disorder. There are also several clinical studies underway studying the limited-use of psychedelics in depression, anxiety, alcohol use disorder, and palliative care.

The Swiss Medical Society for Psycholytic Therapy (SÄPT) was founded in 1985. It has developed into a specialist society with currently around 120 members, mainly from Switzerland and Germany. Its statutory purpose is to make psychoactive substances available for practical psychotherapeutic use,

to control their use, to stimulate further research and to provide the theoretical and practical training necessary for their use.

The approach adopted between federal regulators, university researchers and medical industry professionals in Switzerland in establishing a pragmatic framework for the limited-use supply of psychedelic products has proven highly successful in delivering positive patient outcomes. This collaboration presents an opportunity to access learnings from the Swiss experience and share with key stakeholders in the Australian healthcare industry for the benefit of patients here.

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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

This announcement contains forward-looking statements with respect to Creso and its respective operations, strategy, investments, financial performance and condition. These statements generally can be identified by use of forward-looking words such as "may", "will", "expect", "estimate", "anticipate", "intends", "believe" or "continue" or the negative thereof or similar variations. The actual results and performance of Creso could differ materially from those expressed or implied by such statements. Such statements are qualified in their entirety by the inherent risks and uncertainties surrounding future expectations. Some important factors that could cause actual results to differ materially from expectations include, among other things, general economic and market factors, competition and government regulation.

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.