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Celadon Pharmaceuticals PLC
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Celadon Pharmaceuticals Plc

("Celadon" or the "Company")

Approval of GMP Registration by MHRA

London, 16 January 2023 - Celadon Pharmaceuticals Plc (AIM: CEL), a UK-based pharmaceutical company focused on the research, cultivation, manufacturing and sale of breakthrough cannabis-based medicines, announces that its Midlands UK facility has now been registered by the UK Medicines and Healthcare products Regulatory Agency ("MHRA") for the Good Manufacturing Practice ("GMP") manufacturing of its cannabis Active Pharmaceutical Ingredient (API).

Highlights

- GMP registration understood to be the first such registration of a UK pharmaceutical facility for high Δ9-tetrahydrocannabinol ("THC") cannabis API since the legalisation of medical cannabis in 2018
- Celadon becomes one of a small number of companies globally with the capability to produce an EU-GMP grade high-THC cannabinoid API
- GMP registration and a Home Office licence is required in order to sell high-THC medicinal cannabis in the UK. Celadon has notified the Home Office to request an update to its existing licence to reflect its GMP status
- GMP registration follows the seven harvests and extractions during 2022 and the MHRA inspection in Q4 2022

GMP is the globally recognised quality standard that is required to manufacture pharmaceutical medicines for human use and clinical trials. It is an essential requirement for the commercialisation of Celadon's medicinal cannabis product, which will be supplied in oil form as an API.

The Directors believe Celadon has now become one of a limited number of companies globally with the approvals in place to cultivate and manufacture EU-GMP grade high-THC medicinal cannabis and is understood to be the first for high-THC API in the UK since medicinal cannabis was legalised in 2018. In the UK currently, patients prescribed medicinal cannabis are reliant on imported product, often facing lengthy delays and high costs.

Celadon's API is manufactured using a proprietary combination of genetics, extraction technology and indoor hydroponic cultivation. Utilising the most advanced controlled environment cultivation allows Celadon to achieve pharmaceutical-level consistency, quality and replicability, having done seven successful harvests to-date, resulting in an EU-GMP-grade product suitable for human use.

Celadon's GMP product and its ongoing R&D programme, make the Company a partner a choice for leading universities, government bodies and global pharmaceutical companies undertaking cannabinoid R&D and drug development.

Celadon will require receipt of confirmation from the Home Office that they have updated its current Home Office licence before they will be able to supply its GMP API to third parties. The Company is informing the Home Office of the receipt of its GMP registration. Celadon's current Home Office licence permits it to legally grow high-THC medicinal cannabis for the purpose of producing test batches of cannabis oil to support its application to the MHRA; during 2022, Celadon achieved seven successful harvests. Whilst there is no guarantee that the Home Office will update the current licence, nor any timeframe for this, the Directors are confident that the licence will be updated in due course. The Company has worked closely with the Home Office for four years, including securing updates to its licence, and had the conversation about updating the licence for GMP at the Home Office's last site inspection.

James Short, Chief Executive Officer of Celadon said:

"*With the receipt of GMP registration, Celadon has joined a very select group of cannabis-focused pharmaceutical companies globally. This is a tremendous milestone for the Company given the significant capital and regulatory requirements in this sector.*

"Today's announcement is the culmination of four years of hard work. I would like to thank the team and our loyal shareholders for their support and belief in our vision as we continue our journey of putting the patient first in ensuring they can access the cannabis-based medicines they so desperately need."

Enquiries:

Celadon Pharmaceuticals Plc	
James Short	Via Powerscourt
Arthur Wakeley	
Canaccord Genuity Limited (Nominated Adviser and Broker)	
Bobbie Hilliam / Andrew Potts / Patrick Dolaghan	+44 (0)20 7523 8000
Powerscourt Group	
Sarah MacLeod / Nick Johnson / Sam Austrums /	+44 (0)20 7250 1446
Ibrahim Khalil	

About Celadon Pharmaceuticals Plc

Celadon Pharmaceuticals Plc is a UK based pharmaceutical company focused on the research, cultivation, manufacturing, and sale of breakthrough cannabis-based medicines. Its primary focus is on improving quality of life for chronic pain sufferers, as well as exploring the potential of cannabis-based medicines for other conditions such as autism. Its 100,000 sq. ft UK facility operates to an EU-GMP standard and comprises indoor hydroponic cultivation, proprietary GMP extraction and manufacturing and an analytical and R&D laboratory. The Company's subsidiary, LVL, owns a MHRA conditionally-approved clinical trial using cannabis based medicinal products to treat chronic pain in the UK. Celadon also has a minority interest in early-stage biopharma Kingdom Therapeutics which is developing a licenced cannabinoid medicine to treat children with Autism Spectrum Disorder.

For further information please visit our website www.celadonpharma.co.uk

This announcement contains inside information for the purposes of article 7 of the Market Abuse Regulation (EU) 596/2014 as amended by regulation 11 of the Market Abuse (Amendment) (EU Exit) Regulations 2019/310. With the publication of this announcement, this information is now considered to be in the public domain.

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