**12 January 2021**

**Diurnal Group plc**
("Diurnal" or the "Company")

**Chronocort® Marketing Authorisation Application Submitted to the UK MHRA**

*Independent UK (MHRA) application to run in parallel with ongoing European (EMA) application, following end of Brexit Transition period*

*Both EMA and MHRA marketing authorisations anticipated in Q1 2021 to address European market*

*Significant opportunity to address unmet patient need in a market estimated at $250 million*

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that an 'in flight' Market Authorisation Application (MAA) has been submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA) for Chronocort® (modified-release hydrocortisone) as a treatment for adult and adolescent patients with the rare condition congenital adrenal hyperplasia (CAH) in Great Britain (England, Wales and Scotland).

The MAA submission follows MHRA guidance following the end of the Brexit Transition Period and follows submission of an MAA to the European Medicines Agency (EMA) in December 2019, which was subsequently validated by the EMA in April 2020 and has continued along its planned review path with a marketing authorisation opinion for Chronocort® approval in the European Economic Area anticipated in Q1 2021.

The submission for the MHRA is based on the same application submitted to the EMA in December 2019, including detailed analysis of data from the Company's Phase 3 study, the largest ever interventional clinical trial in CAH, an open-label safety extension study of Chronocort® and written formal Scientific Advice received in April 2019 confirming the clinical and regulatory pathway for Chronocort® as a treatment for patients with CAH. In parallel with the MHRA submission, Diurnal will seek confirmation of British Orphan Drug Status for Chronocort® in CAH, which requires the Company to demonstrate significant clinical benefit for the product compared to existing therapies.

Should Chronocort® be approved, it will provide the potential for life-long treatment across Europe, with patients commencing treatment with Alkindi® (hydrocortisone granules in capsules for opening), the Company's approved paediatric product, transitioning to Chronocort® in adolescence and continuing with Chronocort® treatment into later life.

**Martin Whitaker, CEO of Diurnal, commented:**
*"We are pleased to announce one of the first submissions of a Marketing Authorisation Application to the MHRA via the "in flight" process. Chronocort® remains on track to be approved by the EMA during Q1 2021, with the MHRA approval also now expected during this period. We look forward to the potential launch of our second product in Great Britain and European Economic Area as we continue to build our commercial portfolio and drive towards becoming a world-leading specialty endocrinology business. There is a significant need for new therapies to improve outcomes for adult patients with CAH, which still results in increased morbidity and mortality worldwide. We believe that Chronocort®, together with our paediatric product Alkindi®, has the potential to provide new treatment options for CAH patients throughout their lives."*

CAH is an orphan condition caused by a block in cortisol production, an essential adrenal steroid hormone required for healthy life. A lack of cortisol in turn causes the over-production of male steroid hormones (androgens). Cortisol deficiency and over-production of androgens can lead to increased mortality, infertility and issues during sexual development, including ambiguous genitalia, precocious puberty and short stature. Sufferers, even if treated, remain at risk of death through an adrenal crisis. The condition is estimated to affect a total of approximately 41,000 patients in Europe, with over 400,000 in the rest of the world.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

**For further information, please visit www.diurnal.co.uk or contact:**


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**Notes to Editors**

**About Chronocort®**

Chronocort® is a modified-release preparation of hydrocortisone that has been specifically designed to mimic the circadian rhythm of cortisol when given in a twice-a-day "toothbrush" regimen (last thing at night before sleep and first thing in the morning on waking) to control androgen excess and chronic fatigue in patients with diseases of cortisol deficiency. The first planned indication for Chronocort® is Congenital Adrenal Hyperplasia (CAH) in adults and adolescents. Chronocort® has been extensively studied in human subjects having completed four Phase I trials, a Phase II trial in 16 CAH patients in the US in 2014, and a Phase III trial in 122 CAH patients in Europe and the US.

**About Congenital Adrenal Hyperplasia**

Congenital adrenal hyperplasia (CAH) is an orphan condition caused by deficiency of adrenal enzymes, most commonly 21-hydroxylase. This enzyme is required to produce the adrenal steroid hormone, cortisol. The block in the cortisol production pathway causes the over-production of male steroid hormones (androgens), which are precursors to cortisol. The condition is congenital (inherited at birth) and affects both sexes. The cortisol deficiency and over-production of male sex hormones can lead to increased mortality, infertility and issues during sexual development including ambiguous genitalia, premature (precocious) sexual development and short stature. Sufferers, even if treated, remain at risk of death through an adrenal crisis.

Current therapy for CAH uses a variety of generic steroids (hydrocortisone, dexamethasone and prednisolone) with no standard treatment regimen. Approximately two-thirds of CAH patients are estimated to have poor disease control, leading to elevated androgen levels. The condition is estimated to affect a total of approximately 41,000 patients in Europe, with over 400,000 in the rest of the world.

**About Diurnal Group plc**

Founded in 2004, Diurnal is a UK-headquartered, European specialty pharma company developing hormone therapeutics for the global market for the life-long treatment of chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency and hypogonadism. Its expertise and innovative research activities focus on circadian-based endocrinology to yield novel product candidates in the rare and chronic endocrine disease arena.

For further information about Diurnal, please visit www.diurnal.co.uk


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