

# Diurnal Group plc

("Diurnal" or the "Company")

# Grant of European Patent for Chronocort<sup>®</sup>

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces the grant of a key patent for Chronocort<sup>®</sup> (modified release hydrocortisone) by the European Patent Office.

EP2814469, entitled "Hydrocortisone controlled-release formulation", is a patent disclosing and claiming the composition of matter and medical use of Chronocort<sup>®</sup> for the treatment of patients with the rare diseases congenital adrenal hyperplasia (CAH) and adrenal insufficiency (AI). The patent provides in-market European protection until 2033 in all designated states of the European Patent Convention. The equivalent patents from the same family are already granted in the UK, Canada, Mexico, New Zealand, Japan, Australia, Israel, South Africa, South Korea and in the US.

The Marketing Authorisation Application (MAA) for Chronocort<sup>®</sup> as a treatment for adolescents and adults with CAH is under review by the European Medicines Agency (EMA) following submission of the MAA dossier in December 2019. The MAA was subsequently validated and accepted for review by the EMA in April 2020 and the outcome of the EMA review is anticipated during Q1 2021.

# Martin Whitaker, CEO of Diurnal, commented:

"With the anticipated approval of Chronocort<sup>®</sup> in Europe later this quarter, we are pleased to receive this patent grant by the European Patent Office. This patent, which builds on our strong global intellectual property position for the product, provides protection in Europe until 2033, supporting our continued commitment to develop Chronocort<sup>®</sup> for the treatment of patients suffering from congenital adrenal hyperplasia and subsequently adrenal insufficiency."

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

### For further information, please visit <u>www.diurnal.co.uk</u> or contact:

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# Notes to Editors

## About Chronocort<sup>®</sup>

Chronocort<sup>®</sup> 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<sup>®</sup> is Congenital Adrenal Hyperplasia (CAH) in adults and adolescents. Chronocort<sup>®</sup> 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 high quality products 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

Date of Preparation: January 2021

Code: CORP-GB-0089