



23 February 2021

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

Chronocort® distribution and marketing agreement with Consilient Health for the Nordics

Further builds Diurnal's distribution platform ahead of anticipated European recommendation for approval of Chronocort® in Q1 2021

Extends relationship with Consilient Health following Benelux Union agreement for Alkindi® and Chronocort®

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that it has extended its distribution arrangements with Consilient Health to include the distribution and marketing of Chronocort® (modified-release hydrocortisone) in the Nordic region (consisting of Sweden, Norway, Denmark, Finland and Iceland).

Under the terms of this agreement, Consilient Health, a pharmaceutical company with a track record in commercialising products for endocrinology, women's health and urology, will receive the exclusive rights to market and sell Chronocort® when approved, in the Nordics. The region represents a significant market opportunity for Diurnal, with around 2,300 adult patients suffering from congenital adrenal hyperplasia (CAH), providing an estimated total market opportunity for Chronocort® of approximately €11.5 million per annum.

Chronocort® is a modified-release preparation of hydrocortisone that is under review by the European Medicines Agency (EMA). Chronocort® is given in a twice-a-day regimen to treat diseases of cortisol deficiency. If regulatory review is favourable, a marketing authorisation opinion for Chronocort® approval in the European Economic Area is anticipated during Q1 2021.

In September 2020, the Company announced that it had entered into an agreement with Consilient Health to cover the distribution and marketing of Alkindi® (hydrocortisone granules in capsules for opening) and Chronocort® in the Benelux Union (consisting of Belgium, the Netherlands, and Luxembourg).

On approval, Diurnal will provide Chronocort® from its established European supply chain for sale by Consilient Health to the Nordics and Benelux Union. This agreement adds to the Company's ongoing strategy for commercialisation of its lead products by optimising market access outside of key European markets through entering marketing and distribution agreements with companies focused on niche and orphan conditions.

Martin Whitaker, Chief Executive Officer of Diurnal, commented:

"We have been impressed with Consilient Health since signing our original contract with them in September 2020 and we look forward to building on this relationship to cover the commercialisation of Chronocort® in the Nordics. With a track record in commercialising products for endocrinology, Consilient Health are well placed to distribute Chronocort® in the Nordics and Benelux Union, if approved, where there is a significant unmet need for adults suffering from CAH. We continue to anticipate a positive regulatory opinion by the EMA during this quarter and today's distribution agreement is in line with our strategy to optimise market access of our products outside of key European markets."

Ahmed Al-Derzi, Chief Executive Officer of Consilient Health, commented:

"We have enjoyed our partnership with Diurnal for the Benelux region that the two parties formed in 2020. Along with the rest of the Consilient Health team, I am delighted to be extending that partnership to include the Nordic region. Diseases of cortisol deficiency have significant unmet need and we feel privileged to work with Diurnal and bring new options to endocrinologists and patients in the Nordics."



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

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Notes to Editors

About Chronocort® (modified-release hydrocortisone)

Chronocort® is a 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 glucocorticoid (steroids including hydrocortisone, dexamethasone, prednisolone and prednisone in the US) 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

About Consilient Health



Established in 2005 with headquarters in Ireland, Consilient Health is an independent, dynamic and rapidly growing pharmaceutical company with a rich heritage of commercialising products in complex markets in therapeutic areas such as women's health, urology and endocrinology. The company has a strategy of partnering with innovative companies to bring medicines to market that serve a clear unmet clinical need.

For further information about Consilient Health, please visit www.consilienthealth.com

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