



13 January 2021

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

Diurnal signs agreement with Er-Kim for the distribution of Alkindi® and Chronocort® in Turkey

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces a distribution agreement with Er-Kim, a leading partner for global biotech and pharma companies seeking to commercialise their products in Turkey. The agreement covers the distribution of the Company's products Alkindi® (hydrocortisone granules in capsules for opening) and Chronocort® (modified-release hydrocortisone). The products will be available for the patients who qualify in Turkey through applicable Early Access programmes for patients with diseases of cortisol deficiency who have no other treatment option.

Under the terms of the agreement, Er-Kim will receive the exclusive rights to distribute, and when approved, market Alkindi® and Chronocort® in Turkey. There are over 8,800 patients estimated to be currently receiving treatment for paediatric Adrenal Insufficiency (AI) and the genetic condition Congenital Adrenal Hyperplasia (CAH).

Alkindi® is already approved in Europe, Israel and Australia and is the first preparation of hydrocortisone (the synthetic version of cortisol) specifically designed for use in children suffering from AI, including the related condition CAH. Alkindi® is known as Alkindi® Sprinkle in the US and was approved by the US Food and Drug Administration in September 2020.

Chronocort® is a modified-release preparation of hydrocortisone that is under review by the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). Chronocort® is given in a twice-a-day regimen to treat diseases of cortisol deficiency. If regulatory review is successful, a marketing authorisation opinion for Chronocort® approval in the European Economic Area (and Great Britain and Northern Ireland) is anticipated during Q1 2021.

Diurnal will provide Alkindi® (and subsequently Chronocort® on approval) from its established European supply chain for sale by Er-Kim. 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, CEO of Diurnal, commented:

"We are pleased to sign this agreement with Er-Kim, who have the local expertise and proven track record in Turkey needed to successfully support requests for Alkindi® and Chronocort® under an Early Access programme. This distribution agreement may help support patient needs in diseases of cortisol deficiency. Working with Er-Kim broadens the future availability of both Alkindi® and Chronocort® outside of our core markets in line with our global strategy. We have been impressed with Er-Kim and believe that our strategy is aligned with theirs as a valued distribution partner."

Cem Zorlular, Chairman and CEO of Er-Kim, commented:

"We are excited to be working with Diurnal to bring Alkindi® and Chronocort® to Turkey where there is a significant unmet medical need for patients with adrenal insufficiency and congenital adrenal hyperplasia. We are both aligned to an objective of making these much needed, high quality medicines available to patients who currently have no other satisfactory option for treatment."

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 Alkindi® (hydrocortisone granules in capsules for opening)

Alkindi® is the first preparation of hydrocortisone specifically designed for use in children suffering from paediatric adrenal insufficiency (AI). Alkindi® is a patented, oral, immediate-release paediatric formulation of hydrocortisone granules in capsules for opening that allows for accurate age-appropriate dosing in children. This therapeutic approach has the potential to help young patients less than eighteen years of age suffering from diseases due to cortisol deficiency including paediatric AI and congenital adrenal hyperplasia (CAH). AI requires life-long treatment and Diurnal's novel approach to product development has the potential to significantly improve these young patients' lives. The European Commission has granted a paediatric use marketing authorisation (PUMA) for Alkindi® as replacement therapy of AI in infants, children and adolescents (from birth to <18 years old) in Europe.

Alkindi® is also approved in Israel and Australia.

Alkindi® is approved and known as Alkindi® Sprinkle in the US where it is licensed and marketed by Eton Pharmaceuticals.

About Paediatric Adrenal Insufficiency

Paediatric AI, including the genetic condition CAH is a condition characterised by deficiency in cortisol, an essential hormone in regulating metabolism and the response to stress. The primary symptoms of AI are chronic fatigue and patients are at risk of adrenal crisis and death if they do not have adequate cortisol replacement. AI is either primary or secondary, with primary AI resulting from diseases intrinsic to the adrenal gland and secondary AI resulting from pituitary diseases where there is a failure of stimulation of the adrenal by the pituitary of the signalling hormone ACTH (adrenocorticotropic hormone).

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

About Er-Kim

Er-Kim is a leading commercial partner for global biotech and pharma companies seeking to commercialise their products in Turkey, Europe and Middle East. In its 40-year of presence, Er-Kim has commercialised over 150 original therapies from more than 50 leading global pharmaceutical companies. Additionally, Er-Kim operates in drug discovery for unmet needs in rare blood diseases and R&D providing cost-effective manufacturing of advanced medicinal products easing the economic burden of the healthcare system.

For further information about Er-Kim, please visit www.erkim-ilac.com.tr/en/

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