

23 April 2021

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

Grant of second European Patent for Alkindi®

Exclusivity extended until 2034

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces the grant of a patent for Alkindi® (hydrocortisone granules in capsules for opening) by the European Patent Office.

EP2978414, entitled "Composition Comprising Hydrocortisone", is a patent disclosing and claiming the composition of Alkindi® for the treatment of paediatric patients with adrenal insufficiency (AI). The patent provides in-market European protection until 2034 in all designated states of the European Patent Convention. The equivalent patents from the same family are already granted in the UK, Japan, Australia, Israel, South Africa, South Korea, China, India, Russia and the US (for Alkindi® Sprinkle).

EP2978414 further expands the Company's strong exclusivity position for Alkindi® in Europe, where Diurnal already has 10 years of data and market exclusivity until 2028 through a paediatric use marketing authorisation granted by the European Commission and previous granted patent EP2780003 claiming medical use of Alkindi® for the treatment of paediatric patients with AI. Alkindi® is approved and marketed as the first preparation of hydrocortisone (the synthetic version of cortisol) specifically designed for use in children suffering from AI and the related condition congenital adrenal hyperplasia.

Martin Whitaker, CEO of Diurnal, commented:

"With the continued commercialisation of Alkindi® being a core focus for Diurnal, 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 2034, supporting our continued commitment to provide Alkindi® to paediatric patients suffering from adrenal insufficiency."

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

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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 known as Alkindi® Sprinkle in the US and was approved by the US Food and Drug Administration (FDA) on 29 September 2020.

About Paediatric Adrenal Insufficiency

Paediatric AI 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 Diurnal Group plc

Diurnal Group plc is a European, UK-headquartered, specialty pharmaceutical company dedicated to developing hormone therapeutics to aid lifelong treatment for rare and chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency, hypogonadism and hypothyroidism. 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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