02 December 2019

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

Alkindi® New Drug Application Submitted to US FDA

US submission follows successful launch in Europe

Approval anticipated in late 2020

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that it has submitted a New Drug Application (NDA), under section 505(b)(2) of the Federal Food Drug and Cosmetic Act, to the US Food and Drug Administration (FDA) for the regulatory approval of Alkindi® Sprinkle (hydrocortisone granules in capsules for opening) as a replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <17 years old) in the US.

The NDA submission follows a positive meeting in Q1 2019 with the FDA which confirmed Diurnal's clinical and regulatory pathway for Alkindi® in the US. The pathway is based on a development programme for Alkindi®, including a study to demonstrate bioequivalence with the US reference product, as well as a safety evaluation and tolerability extension study in Europe, which provides valuable long-term exposure data in support of market access in the US. The studies were completed in 2018. Regulatory approval of Alkindi® in the US is anticipated in late 2020.

Diurnal will also request the confirmation of Orphan Drug Status for Alkindi® in paediatric AI, which requires the Company to demonstrate significant clinical benefit for the product compared to existing therapies. In addition, Diurnal continues to progress discussions with potential partners for Alkindi® in the US to optimise market access for patients.

Martin Whitaker, CEO of Diurnal, commented:
"The submission of a New Drug Application for Alkindi® in the US builds on the successful launch of the product in Europe and further validates our vision of becoming a world-leading endocrinology specialty pharmaceutical company. If approved, Alkindi® will provide a major breakthrough in the US as the only licensed treatment specifically designed for use in children with adrenal insufficiency, where there is a significant unmet patient need. We look forward to working closely with the FDA to bring this important product to patients."

Paediatric AI is a condition characterised by deficiency in cortisol, an essential hormone in regulating growth, metabolism and the response to stress. Paediatric AI has been identified as an orphan disease in the US where there are estimated to be approximately 4,500 sufferers under the age of 17. Untreated, the disease is associated with significant morbidity and increased mortality. Alkindi® has the potential to be the first pharmaceutically defined dose and consistent formulation of hydrocortisone (the synthetic version of cortisol) designed specifically for paediatric patients.

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 seventeen years of age suffering from diseases due to cortisol deficiency including paediatric AI and congenital adrenal hyperplasia (CAH) in the US. 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.

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 Diurnal Group plc
Founded in 2004, Diurnal is a UK-based specialty pharma company developing high quality products for the global market for the life-long treatment of chronic endocrine conditions, including congenital adrenal hyperplasia and adrenal insufficiency. 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: November 2019 Code: CORP-GB-0045.