

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

Licencing agreement with Eton Pharmaceuticals for Alkindi[®] extended to Canada

Expands Alkindi[®] availability outside of key European and US commercial markets

Grant of second Alkindi[®] patent in Canada

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that it has extended its exclusive licence arrangement for Alkindi[®] (hydrocortisone granules in capsules for opening) with Eton Pharmaceuticals, Inc. ("Eton") to include Canada. In addition, the Company has been granted a key Canadian patent (No: CA2854717) claiming method of treatment for Alkindi[®].

In March 2020, Diurnal entered into an exclusive licence agreement for Alkindi[®] Sprinkle (as Alkindi[®] is known in the US) in the US with Eton, a specialty pharmaceutical company focused on developing and commercialising innovative treatments for rare paediatric diseases. Following approval by the US Food and Drug Administration, Eton announced in November 2020 that Alkindi[®] Sprinkle is available for sale and distribution in the US.

Under the terms of the new licence agreement, Eton will be responsible for obtaining registration for Alkindi[®] in Canada for the treatment of paediatric patients suffering from adrenal insufficiency and for all commercialisation activities, including pricing and reimbursement. Eton will initially utilise product from Diurnal's European supply chain, with an option to establish its own supply chain in the future. Diurnal will receive a royalty on future sales in Canada.

CA2854717, entitled "Treatment of Adrenal Insufficiency in Children", is a patent disclosing and claiming method of treatment for Alkindi[®] and, together with granted Canadian patent (No: CA2909060 claiming the composition of Alkindi[®]), provides patent exclusivity in the territory until 2034. The corresponding US patents have already been granted.

Martin Whitaker, CEO of Diurnal, commented:

"Following the approval of Alkindi[®] Sprinkle in the US there has been significant interest in the product from physicians and patient groups in Canada. We continue to be impressed by Eton's enthusiasm and vision for Alkindi[®] Sprinkle and are pleased to extend our collaboration to potentially bring the product to paediatric patients in Canada suffering with adrenal insufficiency, where there is a significant unmet patient need. This latest deal further broadens the strong exclusivity position and future availability of Alkindi[®] outside of our core markets in line with our global strategy."

Sean Brynjelsen, CEO of Eton, commented:

"We are excited to expand our partnership with Diurnal to include the Canadian market. We look forward to making the product available to Canadian patients as quickly as possible and building off of the early success we have experienced marketing Alkindi[®] Sprinkle in the United States.".

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 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 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 known as Alkindi[®] Sprinkle in the US and was approved by the US Food and Drug Administration (FDA) on 29 September 2020. Alkindi[®] is also approved in Israel and Australia.

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-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

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