21 October 2020

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

Market Authorisation Application for Alkindi® submitted to Swissmedic

Partner in Switzerland, EffRx Pharmaceuticals, expects market launch by 2022

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that the Company's marketing and distribution partner in Switzerland, EffRx Pharmaceuticals (EffRx), has submitted a Market Authorisation Application (MAA) to Swissmedic for the registration of Alkindi® (hydrocortisone granules in capsules for opening) in Switzerland.

The MAA submission to Swissmedic for Alkindi® is based on the European regulatory dossier and published clinical trial data, with EffRx expecting potential market launch in Switzerland by 2022. There are approximately 200 patients in Switzerland suffering from paediatric AI, providing an estimated total market opportunity for Alkindi® of approximately $1 million per annum. As previously announced under the terms of the agreement, EffRx will receive the exclusive rights to market and sell Alkindi® in Switzerland once registered.

Alkindi® is already approved and marketed in Europe 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.

Diurnal will provide EffRx with product for sale from its established European supply chain and forms part of 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 see the submission of a MAA for Alkindi® in Switzerland by EffRx. Today's announcement is yet further validation of the quality of our products and broadens the future availability of Alkindi® outside our core markets in line with our global strategy. We look forward to working with EffRx to make Alkindi® available to patients suffering from paediatric AI in Switzerland."

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

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, 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 high quality products 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 EffRx Pharmaceuticals

EffRx Pharmaceuticals is a commercial-stage pharmaceutical company focused on the late stage development and commercialisation of prescription medications for niche and orphan indications. The business model is centred around providing superior clinical and commercial value propositions for physicians, payers and patients. EffRx pro-actively seeks in-licensing opportunities for Europe in niche therapeutic areas, with a primary interest for rare diseases, where EffRx has received an orphan drug designation (ODD) from the FDA for a pipeline asset.

For further information about EffRx Pharmaceuticals, please visit www.effrx.com

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