EffRx Pharmaceuticals Signs Exclusive License Agreement with Diurnal for the Registration and Commercialization of Alkindi® and Submits Market Authorization Application in Switzerland

FREIENBACH, Switzerland (BUSINESS WIRE)-– EffRx Pharmaceuticals SA, a commercial-stage company that commercializes niche and orphan medicines in Switzerland and Europe, today announced it has recently entered into an exclusive license agreement with Diurnal Group plc, a specialty pharmaceutical company targeting patient needs in chronic endocrine diseases, for the registration and commercialization of Alkindi® for pediatric adrenocortical insufficiency (AI) in Switzerland. Under the terms of the agreement EffRx has received the exclusive rights to register and commercialize Alkindi® in Switzerland.

Alkindi® is the first preparation of hydrocortisone specifically designed for use in children suffering from paediatric adrenocortical 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 pediatric AI and the related condition congenital adrenal hyperplasia (CAH).

Alkindi® is already approved and marketed in the European Union and is the first preparation of hydrocortisone specifically designed for use in children suffering from AI. On September 29th, 2020 the US Food and Drug Administration (FDA) has also approved Alkindi® for AI.

EffRx has recently submitted to Swissmedic (Switzerland) a Market Authorization Application for the registration of Alkindi®. Pending successful regulatory registration, this new treatment approach is expected to be available on the Swiss market by 2022. In Switzerland there are approximately 200 patients suffering from pediatric AI.

"*We are extremely pleased to announce this partnership with Diurnal which demonstrates EffRx capability to expand its portfolio with promising niche and orphan medicines*", commented Lorenzo Bosisio, CEO of EffRx Pharmaceuticals. "*We look forward to bringing this novel therapeutic approach to Switzerland. We are confident that Alkindi® provides a tangible advancement for young patients suffering from AI and their carers.*"

Martin Whitaker, CEO of Diurnal, commented: *"This partnership with EffRx further validates the quality of our products and broadens the future availability of Alkindi®. EffRx is well-placed to register and market our product Alkindi® in Switzerland. We have made strong progress with the sales of Alkindi® across Europe since its approval and subsequent launch in 2018, and we are confident this agreement will enable further growth."*

Pediatric 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 EffRx Pharmaceuticals

EffRx Pharmaceuticals is a commercial-stage pharmaceutical company focused on the late stage development and commercialization of prescription medications for niche and orphan indications. The business model is centered 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.

EffRx's go-to-market competence is proven by the development, launch and lucrative expansion of Binosto® in a highly competitive European market. Our lead commercialized product, Binosto® for the treatment of osteoporosis, is marketed in the US as well as selected European and Asian countries.

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

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