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[DIURNAL APPOINTS CLINIGEN TO LAUNCH A EUROPEAN PATIENT ACCESS PROGRAMME FOR INFACORT® AND CHRONOCORT®](#)

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Infrastructure and supply chain now in place to provide Infacort® and Chronocort® as unlicensed medicines to patients on a Named Patient basis

Diurnal Group plc [AIM: DNL], the specialty pharmaceutical company targeting patient needs in chronic endocrine [hormonal] diseases, announces a partnership with Clinigen Group plc's [AIM: CLIN] IDIS Managed Access ["IDIS"] division to launch a Patient Access programme in Europe for the Company's lead products, Infacort® and Chronocort®, for patients with diseases of cortisol deficiency.

The Patient Access programme will enable physicians in Europe to prescribe Infacort® and Chronocort® as unlicensed medicines on a Named Patient basis for patients who have no other treatment options, ahead of anticipated European approval and commercial launch of the products.

Infacort® is a preparation of hydrocortisone [the synthetic version of cortisol] specifically designed for use in children suffering from adrenal insufficiency [AI], including the related disease, congenital adrenal hyperplasia [CAH]. Chronocort® is a modified release hydrocortisone preparation that has been designed to mimic the natural circadian rhythm of cortisol when given in a twice-a-day "toothbrush" regimen for the treatment of adult CAH.

AI and CAH are characterised by deficiency in cortisol, an essential hormone in regulating metabolism and the response to stress. AI is identified as a rare disease in Europe where there are estimated to be approximately 4,000 sufferers younger than the age of six. Poor control of the disease can result in premature puberty in young children, virilisation in girls and chronic fatigue leading to a poor quality of life in adulthood resulting in increased morbidity and mortality.

CAH is the most common inherited [genetic] hormone disorder affecting both men and women. Approximately two thirds of CAH patients are estimated to have poor disease control. The condition is estimated to affect approximately 51,000 patients in Europe. Poor disease control can lead to increased mortality, infertility and severe development defects including ambiguous genitalia, premature sexual development and short stature. Sufferers, even if treated, remain at risk of death through an adrenal crisis.

Martin Whitaker, CEO of Diurnal, commented:

“Our first product, Infacort®, is currently undergoing regulatory review with the EMA. Whilst this is ongoing, we are focused on putting in place the appropriate infrastructure to ensure that patients with cortisol deficiency but no other treatment options can access this medicine as efficiently as possible. As a global leader in providing unlicensed medicines to patients on a Named Patient basis, Clinigen is well placed to help us make Infacort® and Chronocort® accessible to patients ahead of their potential approval.”

Steve Glass, Group Managing Director of Clinigen, said:

“The effective treatment of patients with CAH and paediatric AI represents a significant unmet need. As the global leader in providing Managed Access programmes, we can leverage our international reach to support these patients by enabling their physicians to access these therapies safely, ethically and quickly, ahead of approval and launch.”

Diurnal submitted a Paediatric Use Marketing Authorisation (PUMA) application for Infacort® to the European Medicines Agency (EMA) in late 2016. Diurnal anticipates that the EMA review process could take up to one year to complete.

Chronocort® is currently in Phase III clinical development with the trial scheduled to complete in 2018. If the results of the Phase III trial are supportive, Diurnal plans to submit Chronocort® for market approval in Europe.

Healthcare Professionals can obtain details about the Infacort® and Chronocort® Patient Access programmes by calling +44 (0) 1283 495 010, or emailing customer.services@clinigengroup.com.

Reference

Date of preparation 16th March 2017 Ref: CH EU-EU-0028

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

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Notes to Editors

About Adrenal Insufficiency Adrenal Insufficiency

[AI] is a condition characterised by deficiency in cortisol, an essential hormone in regulating metabolism and the response to stress. AI has been identified as a rare disease in Europe where there are estimated to be approximately 4,000 sufferers younger than the age of six. Currently there are no licensed hydrocortisone preparations in Europe specifically designed to treat these young patients. These children are often administered compounded adult tablets or other unlicensed products. Poor control of disease can result in precocious puberty in young children, virilisation in girls and chronic fatigue leading to a poor quality of life in adulthood resulting in increased morbidity and mortality.

About Congenital Adrenal Hyperplasia

Congenital Adrenal Hyperplasia [“CAH”] is an orphan condition usually caused by deficiency of the enzyme 21-hydroxylase. This enzyme is required to produce the adrenal steroid hormone, cortisol. The block in the cortisol production pathway causes the over-production of male steroid hormones [androgens], which are precursors to cortisol. The condition is congenital [inherited at birth] and affects both sexes. The cortisol deficiency and over-production of male sex hormones can lead to increased mortality, infertility and severe development defects including ambiguous genitalia, premature [precocious] sexual development and short stature. Sufferers, even if treated, remain at risk of death through an adrenal crisis.

Approximately two thirds of CAH patients are estimated to have poor disease control, leading to elevated androgen levels. The condition is estimated to affect approximately 71,000 patients in Europe [51,000] and the US [20,000], with approximately 405,000 in the rest of the world.

Current therapy for CAH uses a combination of generic steroids [hydrocortisone, dexamethasone and prednisolone] and, at best, these adequately treat approximately one third of CAH patients. Other therapies being developed are at an early stage of development and not expected to receive approval in the short-term.

About Infacort®

Infacort® represents the first preparation of hydrocortisone specifically designed for use in children suffering from AI. It is a patented, immediate-release, oral, paediatric formulation of hydrocortisone that allows for age-appropriate dosing in children. This therapeutic approach has the potential to help young patients less than six year of age suffering from diseases due to cortisol deficiency including adrenal insufficiency and congenital adrenal hyperplasia. AI requires life-long treatment and Diurnal’s novel approach to product development has the potential to significantly improve these young patients’ lives. Diurnal has already submitted for market authorisation to the European Medicines Agency via the Paediatric Use Marketing Authorisation [PUMA] route in late 2016.

About Chronocort®

Chronocort® is a modified release hydrocortisone preparation that has been designed to mimic the natural circadian rhythm of cortisol when given in a twice-a-day “toothbrush” regimen (last thing at night before sleep and first thing in the morning on waking). Chronocort has been granted orphan drug designations in Europe and the US in the treatment of Congenital Adrenal Hyperplasia (“CAH”) and Adrenal Insufficiency (“AI”). The first planned indication for Chronocort® is CAH. Chronocort® has completed three Phase I trials in 2011, 2012 and 2015 (food effects study) and a Phase II trial in CAH patients in 2014, and is currently in Phase III trials in Europe.

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing access to medicines. Its mission is to deliver the right medicine to the right patient at the right time.

The Group consists of five synergistic businesses focused in three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

Clinigen Clinical Trial Services is the global market leader in the management and supply of commercial medicines for clinical trials.

The Group is also the trusted global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need, through three of its divisions: Idis Managed Access runs early access programmes for innovative new medicines. Idis Global Access and Link Healthcare work directly with healthcare professionals to enable compliant access to unlicensed medicines on a global basis and niche essential licensed and generic medicines across Australasia, Africa and Asia (AAA region).

Clinigen Specialty Pharmaceuticals acquires global rights, revitalises and markets its own portfolio of niche hospital commercial products.

For more information, please visit www.clinigengroup.com.

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 [1]

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