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RNS Reach

Clinigen and Diurnal partner for European Managed Access programme for Infacort® and Chronocort®

Clinigen Group plc's (AIM: CLIN, 'Clinigen' or the 'Group') Idis Managed Access (MA) division and Diurnal Group plc (AIM: DNL, 'Diurnal'), have partnered to launch a Managed Access programme in Europe for Infacort® to treat paediatric patients with adrenal insufficiency (AI) and Chronocort® to treat patients with congenital adrenal hyperplasia (CAH).

CAH is the most common inherited hormone disorder affecting both men and women. It is caused by genetic mutations of the enzymes in the adrenal gland that synthesise steroid hormones. Patients with CAH have a deficiency of the stress hormone, cortisol. Their body's response to this is for the adrenal glands to produce more of the male steroid hormones (androgens), which, in excess levels, are harmful to patients.

Cortisol deficiency and over-production of androgens can lead to increased mortality, infertility and severe development defects, including ambiguous genitalia, precocious puberty and short stature.

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 51,000 patients in Europe.

Infacort® has been specifically designed for use in children suffering from AI and has the potential to help young patients less than six years of age with cortisol deficiency including AI and CAH. Diurnal submitted a Paediatric Use Marketing Authorisation (PUMA) application for Infacort® to the European Medicines Agency (EMA) in late 2016.

Chronocort® has orphan drug designation in Europe and the US for the treatment of CAH and AI in adult patients. Chronocort® is currently in Phase III clinical development and therefore not yet commercially available.

Run by Idis MA, the Managed Access programme will enable physicians in the European Union to access Infacort® and Chronocort® as unlicensed medicines on an individual named patient basis for patients who have no other treatment options, ahead of European approval and commercial launch.

Steve Glass, Chief Commercial Officer, North America and Europe 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."

Martin Whitaker, Chief Executive Officer of Diurnal said:

"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."

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

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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 medicines.

For more information, please visit www.clinigengroup.com

About Diurnal
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