

Från: DuoCort <no-reply@mynewsdesk.com>
Ämne: **DuoCort Pharma and Clinigen sign agreement on named patient programme for Plenadren**
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DuoCort



DuoCort Pharma and Clinigen sign agreement on named patient programme for Plenadren

DuoCort - Apr 28, 2011 07:00 CEST



Helsingborg/ Burton on Trent April 28th 2011– The Swedish specialty pharma company, [DuoCort Pharma](#) and UK-based Clinigen, the global provider of specialist and unlicensed medicines, announce that they have concluded an agreement whereby Clinigen will manage a Named Patient Programme for Plenadren, a novel treatment for Addison´s disease. The product has orphan status in Europe and the USA and is currently in the European Union (EU) registration process for marketing authorisation.

Although cortisol replacement therapy for adrenal insufficiency has been around for a long time, several studies have recorded premature death, impaired quality of life, increased risk of cardiovascular diseases and decreased bone mineral density in these patients. Existing replacement therapies, unable to mimic cortisol's normal diurnal release profiles, are viewed as the likely cause of these outcomes. The new treatment from DuoCort Pharma has a physiological release profile which mimics the body's natural release of cortisol, thereby improving treatment outcomes.

The Agreement with DuoCort Pharma provides Named Patient Supply of Plenadren into the EU.

Commenting on the Agreement, Mark Corbett, Clinigen's Global Strategic Planning Director said: "We are delighted that DuoCort has selected Clinigen to manage a Named Patient Programme for Plenadren. Our team has extensive global experience of developing innovative, flexible and effective Named Patient Programmes that facilitate and address the needs of patients, health professionals, regulatory authorities and biopharmaceutical companies. We look forward to working with DuoCort".

"We are very pleased to be working with Clinigen who are an experienced provider of specialist medicines enabling the access of Plenadren to meet the unmet needs for the patients with Addison´s disease." commented Maria Forss, CEO of DuoCort Pharma.

Clinicians and Pharmacists wishing to access Plenadren may contact Clinigen:

T: +44 (0) 1283 494340 F: +44 (0) 1283 494341

E: customer.services@clinigen.co.uk

About Adrenal insufficiency

Patients suffering from adrenal insufficiency (cortisol deficiency) are unable to produce their own cortisol. To survive, they need replacement therapy with hydrocortisone. Adrenal insufficiency is a rare disease that affects patients in their active years. Because it is a chronic condition, they require this life-saving therapy throughout their lives. Treatment of adrenal insufficiency involves replacing, or substituting, the hormones that the patient's own adrenal glands are not making. Cortisol is replaced using hydrocortisone, the synthetic form of cortisol.

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About DuoCort Pharma

DuoCort Pharma is a drug development company focused on improving glucocorticoid therapy. The company has its origins among researchers at the Sahlgrenska University Hospital in Gothenburg and at Uppsala University in Sweden. DuoCort has developed an improved glucocorticoid replacement therapy for patients with adrenal insufficiency, a rare disease for which DuoCort has orphan drug designations in Europe and the USA. The new product is a once daily dual-release hydrocortisone oral tablet. It has an outer layer that releases the drug immediately and an inner core that releases the drug over the day to mimic the body's own release profile of cortisol. The tablets come in both 5 mg and 20 mg sizes. For more information please visit www.duocort.com.

DuoCort Pharma is a project company of the life science incubator PULS. For more information visit www.pulsinvest.se.

www.duocort.com.

About Clinigen

Clinigen provides global Early Access and Named Patient Solutions. A UK-based company, Clinigen develops solid, flexible and effective partnerships to facilitate and address the needs of patients, healthcare professionals and biopharmaceutical companies.

The Clinigen Group Companies provide services throughout the entire pharmaceutical life cycle, addressing the unmet medical needs of patients by delivering unparalleled solutions.

www.clinigen.co.uk

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 [PDF documents](#)  [Word document](#)

Related material

Press Releases

[DuoCort Pharma and Recipharm start innovative collaboration](#)

Oct 27, 2010 06:30 CEST

DuoCort Pharma announces it has concluded an agreement with Recipharm under which Recipharm is set to scale-up the manufacturing of DuoCort's tablets to commercial scale as DuoCort Pharma prepares for market entry with its orphan drug for the treatment of Addison's disease.

[Better quality of life with new orphan drug for Addison's disease](#)

Jun 21, 2010 18:00 CEST

DuoCort Pharma's new physiological treatment for adrenal insufficiency improves patients' quality of life. The company has also developed methods to optimize the dosage regimen which also contributes to an improvement in therapy over time. The Swedish pharmaceutical company presents this new data from its phase II/III trial at the 92nd annual ENDO congress in San Diego today.

[DuoCort seeks European market authorisation for orphan drug](#)

Jun 17, 2010 06:30 CEST

The Swedish speciality pharma company DuoCort Pharma takes a step closer to the market by applying for market authorisation in EU for its new treatment for the rare and life threatening disease adrenal insufficiency, often referred to as Addison's disease.

[New chronotherapy for Addison's disease](#)

Jun 29, 2009 06:30 CEST

Helsingborg June 29th 2009- DuoCort publishes data from its Phase I study for the rare and life threatening disease adrenal insufficiency. The release profile of DuoCort's new form of treatment with once-a-day hydrocortisone dosing resembles the physiological secretion pattern. The data is published today in the European Journal of Endocrinology, a leading scientific journal for endocrinology.

[Successful phase II/III trial of new therapy for Addison's disease](#)

Jun 12, 2009 06:00 CEST

Helsingborg/ Washington DC June 12th 2009- DuoCort gained promising data from its Phase II/III study for the rare and life threatening disease adrenal insufficiency. DuoCort's new form of physiological treatment with once daily dosing show improved cardiovascular measures compared to standard hydrocortisone given thrice daily. The company presents the data at the ENDO congress in Washington DC.

[DuoCort Gets Orphan Drug Designation in the US for Treatment of Adrenal Insufficiency](#)

Jun 27, 2008 06:30 CEST

Helsingborg, Sweden, June 27, 2008 - DuoCort Pharma AB, a privately held Swedish drug development company, today announced that the US Food and Drug Administration (FDA) has granted an Orphan Drug Designation for the company's DuoCortTM hydrocortisone dual-release oral tablet in development for the treatment of adrenal insufficiency

Videos



[DuoCort-A story about a pill](#)

DuoCort has developed an improved treatment for patients with adrenal insufficiency, a rare disease for which DuoCort has orphan drug designations in Europe and the USA. The new treatment is a dual release. This means it has an outer layer that immediately releases the drug and an inner core that releases the drug over the day to mimic the body's own release of cortisol.

Length 2:48

News

[Trademark granted in EU for DuoCort's new Addison's treatment](#)

Mar 15, 2011 06:30 CET

DuoCort's new form of physiological treatment for the rare and life threatening disease adrenal insufficiency, also called Addison's disease, was recently granted a registered Community Trademark within the EU. The trademark is PLENADREN. The product, which has orphan status in Europe and the USA, is currently in the European Union (EU) registration process for marketing authorisation.

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