

New chronotherapy for Addison´s disease

Helsingborg Sweden 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 closely resembles the physiological secretion pattern. The data is published today in the European Journal of Endocrinology, a leading scientific journal for endocrinology. <http://www.eje.org/cgi/content/abstract/161/1/119>

DuoCort´s new drug has been developed to produce a **physiological release profile** that mimics the body´s natural secretion pattern of cortisol to improve outcomes for patients. Results from the **phase I** study in healthy volunteers, evaluating the safety and pharmacokinetics of the new hydrocortisone tablet, show a physiological diurnal serum cortisol profile after single-dose administration that mimics the natural secretion pattern of cortisol. The new **DuoCort** therapy showed no absorption failure allowing it to be safely used in patients with adrenal insufficiency. Data from a subsequent **phase II/III** trial in patients with primary **adrenal insufficiency** or **Addison´s disease**, presented at a scientific congress in June confirmed the findings in the **phase I** study and showed the new therapy to be well tolerated and safe.

Endocrinology Professor and Chief Medical Officer of DuoCort, Gudmundur Johannsson says, "We are very pleased with the outcome of the **Phase I trial**, especially as there was little inter- or intra-individual variability in the pharmacokinetics and the drug release profiles look very like the physiological release profile of cortisol in healthy individuals. This new more physiological **chronotherapy** has excellent potential to significantly improve **cortisol replacement** in all types of **adrenal insufficiency**"

Adrenal insufficiency in its untreated state is a highly deadly condition. Current therapy is long outmoded, with no major drug improvements since at least the 1960s.

Increasing interest in **adrenal insufficiency** during the past 10 years has resulted in studies showing premature death, compromised quality of life, increased cardiovascular risk and reduced bone mineral density among patients with **adrenal insufficiency**. The likely cause is the highly un-physiological **glucocorticoid replacement** delivered by even the best therapy available today. The large unmet medical need is to improve therapy by mimicking the sizable diurnal variation in serum cortisol that normally occurs. DuoCort seeks to

do so by providing a so-called **chronotherapy with once-a-day dosing to further enhance the physiological profile.**

About Adrenal insufficiency

Patients suffering from **adrenal insufficiency (cortisol deficiency)** are unable to produce their own **cortisol** and need replacement therapy to survive. Adrenal insufficiency is a **rare disease** that affects patients in their active years and, 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 adrenal glands are not making. Cortisol is replaced using **hydrocortisone**, the synthetic form of cortisol, and sometimes with other corticosteroids.

There are different types of **adrenal insufficiency: primary adrenal insufficiency** also called **Addison´s disease**, secondary adrenal insufficiency and **CAH- congenital adrenal hyperplasia**.

About chronotherapy

Coordinating biological rhythms (chronobiology) with medical treatment is called **chronotherapy**. It takes into account the body's biological rhythms in determining the timing--and sometimes the amount--of medication to optimize a drug's desired effects and minimize its undesired ones.

Chronotherapy for the most part is not about new drug substances but about **using medicines in new ways, better attuned to the body's needs.**

Designing a drug so its release into the bloodstream has a particular release pattern or using pumps that deliver medicine at specified intervals are some of the innovations that may reap important benefits.

About DuoCort

DuoCort is a **drug development company** focused on improving **glucocorticoid therapy** in several areas of medical need. The company has its origins among researchers at the Sahlgrenska University Hospital in Gothenburg and at Uppsala University in Sweden. DuoCort is **developing 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, a once daily dual-release hydrocortisone oral tablet that comes in both 5 mg and 20 mg sizes, is being developed by DuoCort Pharma AB, a wholly-owned subsidiary. For more information on **DuoCort** please visit www.duocort.com

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