

## **DuoCort seeks European market authorisation for orphan drug**

*Helsingborg June 17<sup>th</sup> 2010- 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.*

The application for market authorisation was submitted to the European Medicines Agency EMA via the centralised procedure. This means that an approved product will get a market authorisation valid in all EU countries plus Norway and Iceland. The process usually takes about a year.

More than 400 patients per million inhabitants suffer from adrenal insufficiency and need life long treatment to replace the hormone cortisol in order to survive.

Although replacement therapy for adrenal insufficiency has been around for a long time, several studies show premature death, impaired quality of life, increased risk of cardiovascular diseases and decreased bone mineral density in these patients. The likely cause is that today´s replacement therapy is outdated and cannot mimic the normal diurnal release profile of cortisol. The new treatment from DuoCort Pharma has a physiological release profile which mimics the body´s own natural release of cortisol. In this way, treatment outcomes are improved for patients.

Gudmundur Johannsson, Professor and senior physician at the Department of Endocrinology, Sahlgrenska University Hospital, Göteborg, Sweden and Chief Medical Officer of DuoCort Pharma, says "This new more physiological therapy has excellent potential to significantly improve cortisol replacement in all types of adrenal insufficiency. The improvement in cardiovascular risk factors combined with a simple dosing regimen will make this a welcome new treatment option to help patients lead a more normal life"

Additional data for the new product will be presented at the major annual congress of endocrinology in the USA next week.

## 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.

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

## 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 on DuoCort please visit [www.duocort.com](http://www.duocort.com)

DuoCort Pharma AB is a project company of the life science incubator PULS. For more information visit [www.pulsinvest.se](http://www.pulsinvest.se).

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