

## Press release

### **DuoCort Pharma receives positive opinion from CHMP for Plenadren®**

*Helsingborg July 22<sup>nd</sup> 2011– The Swedish specialty pharma company, DuoCort Pharma announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency issued a positive opinion recommending marketing authorisation of its product Plenadren, a novel treatment for adrenal insufficiency.*

Following the formal decision by the European Commission Plenadren® can be marketed in 27 countries i.e. the European Union, Iceland and Norway. DuoCort Pharma anticipates a final positive decision from the Commission in the coming three months as the Commission generally follows the advice from the CHMP.

Commenting on the positive opinion from CHMP, Maria Forss, CEO of DuoCort Pharma said: “We are very pleased that the CHMP has recognized the therapeutic benefits of Plenadren in addressing the unmet needs of the patients suffering from adrenal insufficiency. We are also thankful for the support from patient organizations and experts throughout the development of Plenadren.”

Developed by DuoCort Pharma, Plenadren is a dual release hydrocortisone replacement therapy designed to better mimic the normal physiological cortisol serum profile in order to improve the outcomes for patients suffering from adrenal insufficiency. Plenadren is given as an oral tablet once daily and has an outer layer immediately releasing hydrocortisone and an inner core releasing the rest of the drug over the day.

Professor Gudmundur Johannsson, at the Department of Endocrinology, Sahlgrenska University Hospital, Gothenburg, Sweden and Chief Medical Officer of DuoCort Pharma, said: “Plenadren is the first true innovation in over 50 years in the treatment of adrenal insufficiency. It offers a welcomed new treatment option to help patients lead a more normal life. Plenadren can improve the treatment for the many of the 200 000 patients in Europe who suffer from adrenal insufficiency who need life-long cortisol replacement therapy for their survival.”

Although cortisol replacement therapy for adrenal insufficiency has been available for many years studies have recorded premature death, impaired quality of life, increased risk of cardiovascular diseases and decreased bone mineral density in treated patients. These data support the short-coming of existing replacement therapies.

## About Adrenal insufficiency

Adrenal insufficiency (cortisol deficiency) is a rare, life-threatening disease that affects patients in their active years. To survive, patients suffering from this disease need lifelong replacement therapy with hydrocortisone. Treatment of adrenal insufficiency involves replacing, or substituting, the hormones that the patient's own adrenal glands are not producing. Cortisol is replaced using hydrocortisone, the synthetic form of cortisol.

## 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 Pharma has developed Plenadren<sup>®</sup>, an improved glucocorticoid replacement therapy for patients with adrenal insufficiency, which is a rare disease. DuoCort Pharma has orphan drug designations in Europe and the USA for Plenadren. Plenadren 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. The tablets come in both 5 mg and 20 mg strengths. For more information please visit [www.duocort.com](http://www.duocort.com).

DuoCort Pharma 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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