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 develop-ment 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

Events

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.

Excerpt from “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....

Maria Forss of DuoCort sent over a .pdf of a European Journal of Endocrinology story “Improving glucocorticoid replacement therapy using a novel modified-release hydrocortisone tablet: a pharmacokinetic study”, which unfortunately is too long to run in the NADF News®. If you would like a copy e-mailed to you, just contact NADFMail@aol.com, and we will send it over.
For a postal mailed copy, please send a check or money order for $3.12 (to cover copy cost and postage) made out to NADF, and we will mail you a copy. (Be sure to include your home address.)

DuoCort presents new data at The Endocrine Society’s annual meeting in the US
Apr 15, 2010 16:33 CEST Time: Jun 19 - Jun 22
Plats: San Diego, California, USA
DuoCort has three accepted abstracts with new data at the annual congress, ENDO, arranged by the American Endocrine Society. The data that will be presented are:
- Quality of life data from the ph II/III trial
- Dose individualisation
- A world wide patient survey with over 1200 respondents

Images DuoCort logo

DuoCort logo

Size 3.6 KB File Format .gif
Image Size 120 x 50 pixels

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

Contacts
Maria Forss - General management of DuoCort Pharma
M Sc BA. Project manager. Former Brand Insight Director in global marketing at AstraZeneca, leading a team of business analysts. Worked in both local and

Gudmundur Johannsson
Chief Medical Officer, M.D, Ph.D, Professor and Senior Physician at the Department of Endocrinology, Sahlgrenska University Hospital, Göteborg, Sweden. He is

Jacob Kaluski
Born 1950, M.Sc. in Pharmacy with more than 30 years of experience from the pharmaceutical industry focusing on international marketing and drug

In a message dated 6/7/10 8:46:44 AM, maria.forss@pulsinvest.se writes:

Dear Melanie

I hope you are well!

As the ENDO congress in San Diego is coming up, I wanted to touch base to hear if you also will be there. It would be nice to catch up over a coffee or so, if you have time.

Meanwhile I attach below information about the abstracts with DuoCort data that will be presented at the congress, including the patient survey that your members participated in.

Kind regards
Maria Forss
CEO
DuoCort Pharma

• Dose Individualization of Cortisol Replacement Therapy in Adrenal Insufficiency with a Dual-Release Hydrocortisone Formulation Using Body Weight and Pharmacokinetic Nomograms Derived from Population Pharmacokinetic Modelling.
  Date: Sunday, June 20, 2010
  Time: 1:30 - 3:30 PM
  Room: Halls D-G, San Diego Convention Center Poster Board Number: P2-677

- Improved Quality of Life in Patients with Primary Adrenal Insufficiency by Using a Novel Once-Daily Dual Release Hydrocortisone Tablet: A Randomised Controlled, Cross-Over Trial.
  Date: Monday, June 21, 2010
  Time: 1:30 - 3:30 PM
  Room: Halls D-G, San Diego Convention Center Poster Board Number: P3-646

• Current Practice and Outcomes in Glucocorticoid Replacement Therapy- A Worldwide Patient Survey
  Date: Monday, June 21, 2010
  Time: 1:30 - 3:30 PM
  Room: Halls D-G, San Diego Convention Center Poster Board Number: P3-644

----- Original Message ----- 
From: NADFMAIL@aol.com
To: "maria forss" <maria.forss@pulsinvest.se>
Sent: Thursday, June 10, 2010 12:34:05 PM GMT -05:00 US/Canada Eastern
Subject: Re: DuoCort at ENDO

Hi Maria,

It's very nice to hear from you. I hope this e-mail finds you doing well.

I would so love to meet you in person, but I'm afraid that I will not be at Endo 2010 in the lovely city of San Diego. :( Dr. Margulies (NADF's Medical Director) might be attending the conference. Maybe you would be able to meet with him there. I will interact with him to see what his schedule is.

Thank you so much for the information. Will any of these items be available electronically?

I will interact with Dr. Margulies about the conference, inform him of your posters and get back to you with his reply.

Have a great time in San Diego. It's a beautiful city with perfect weather. :D

Melanie :D

Melanie Wong
Executive Director
In a message dated 6/10/10 8:20:31 PM, Dr. Margulies writes:

Hi:

Yes, I will be there. I'll try to stop by for the posters.

Paul

In a message dated 6/16/10 11:30:24 PM, maria.forss@pulsinvest.se writes:

DuoCort

DuoCort seeks European market authorisation for orphan drug
Jun 17, 2010 06:30 CEST

Helsingborg June 17th 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.

Contact information

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Maria Forss, CEO tel +46 70-967 00 07
Jacob Kaluski, Chairman of the Board of Directors, tel +46 70-356 56 65

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

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

"DuoCort

Better quality of life with new orphan drug for Addison’s disease
Jun 21, 2010 18:00 CEST Duocort_logo_small

Helsingborg / San Diego June 21st 2010- DuoCort Pharma´s new physiological treatment for adrenal insufficiency improves patients’ quality of life. The Swedish pharmaceutical company presents new data from its phase II/III trial at the 92nd annual ENDO congress in San Diego today.

The new treatment from DuoCort Pharma has a more physiological release profile which mimics the natural secretion pattern of cortisol. In this way, treatment outcome and quality of life are improved for patients. The company has also developed methods to optimize the dosage regimen which also contributes to an improvement in therapy over time.

DuoCort Pharma is also presenting the results of a worldwide survey of 1200 adrenal insufficiency patients. Over 60% report that current therapy results in reduced and compromised quality of life necessitating changes to physical activity, social life, work life and family life. Three quarters are concerned about long term side effects of their replacement therapy such as osteoporosis, obesity, fatigue and cardiovascular morbidity, in that order. These data demonstrate a large need for improvement in glucocorticoid replacement therapy.
These results confirm several earlier studies showing premature death, compromised quality of life, and increased cardiovascular risk factors in patients treated for adrenal insufficiency. The likely reason for these outcomes is the very outdated replacement treatment that is used today which cannot mimic the normal diurnal cortisol profile.

Gudmundur Johannsson, professor and senior physician at the Department of Endocrinology, Sahlgrenska University Hospital, Gothenburg, Sweden and Chief Medical Officer of DuoCort Pharma, says “This new more physiological therapy has excellent potential to significantly improve cortisol replacement for over 200 000 patients in Europe and more than 125 000 patients in the US who suffer from adrenal insufficiency and need life-long cortisol replacement therapy for survival. The improvement in cardiovascular risk factors, well-being and quality of life as well as a simplified and more individualised dosage regimen will make this a welcome new treatment option to help patients lead a more normal life.”

Earlier this year a market authorisation application was filed with the European Medicines Agency, which is an important step towards market introduction for the new orphan drug from DuoCort Pharma.

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.

For more details on the data please also see:  

Contact information

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Jacob Kaluski, Chairman of the Board of Directors, tel +46 70-356 56 65

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**CHRONOCORT UPDATE**

Forwarded to NADF, courtesy of Katherine G. White of the U.K.’s Addison’s Disease Self-Help Group (ADSHG)

“Chronocort has been repatriated to Diurnal Ltd, a University of Sheffield spinout. The rights have not been sold to Pfizer, although Pfizer have invested in the company. The development program is continuing.”