About Cushing's Syndrome

Endogenous Cushing's syndrome (CS) is a rare but serious and potentially lethal endocrine disease caused by chronic elevated cortisol exposure. Subjects with uncontrolled disease are seriously ill and have a 2- to 4-fold higher mortality rate than age- and gender-matched controls, mainly due to metabolic and cardiovascular complications. Treatment options for CS include surgery, radiation therapy, and medical treatment.

About Strongbridge Biopharma

Strongbridge Biopharma is a global, commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. Cortendo AB is a Strongbridge Biopharma company and the sponsor of the LOGICS study. This means Cortendo AB planned and organized this study and will also collect and analyze the data from the study.

Is There Any Cost for Participation?

There are no costs for subjects to participate in this study. All costs for examinations, assessments, laboratory testing, and study medications are paid by the sponsor of this study. The sponsor will reimburse all reasonable costs the subjects might have due to study participation (e.g. travel to the site visits). They may be compensated for their time and inconvenience according to local regulations.

The safety and efficacy of levoketoconazole for the treatment of endogenous Cushing's syndrome have not been established.

STRONGBRIDGE BIOPHARMA

www.CushingsTrial.com

www.strongbridgebio.com

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It Starts With YOU!

Join the Research Effort for

ENDOGENOUS CUSHING'S SYNDROME.

Consider the LOGICS Study.

LOGICS

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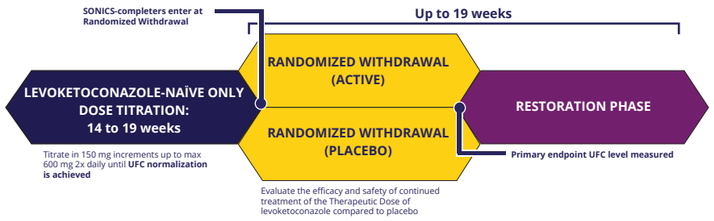
What is LOGICS?

LOGICS is a global, phase 3 study to compare the effects of levoketoconazole (COR-003) compared to a placebo (a pill with inactive ingredients) on people with endogenous Cushing's syndrome. The study is being conducted in more than 11 countries in North America and Europe and is the second study sponsored by Cortendo AB in this condition; the first was known as SONICS.

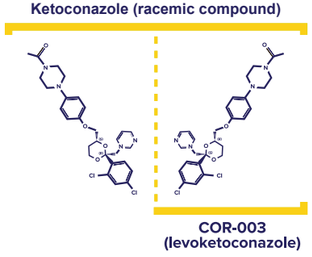
Subjects who have previously participated in SONICS or have never received levoketoconazole before are eligible to participate. Subjects with both pituitary (Cushing's disease) and non-pituitary causes of Cushing's syndrome may be eligible to participate. Study will be conducted in 3 parts as follows:

LOGICS Trial Design



Primary Endpoints	To determine the effect of withdrawing to placebo versus continuing treatment with levoketoconazole on the cortisol (UFC) therapeutic response previously established during open-label levoketoconazole therapy.

COR-003 (levoketoconazole) structure



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Who Is Eligible to Participate?

The LOGICS study is now recruiting subjects who are at least 18 years of age and have confirmed newly diagnosed, persistent, or recurrent endogenous Cushing's syndrome (CS), and are not candidates for surgery or radiotherapy.

To be eligible for enrollment in this study, a subject must meet these and other inclusion criteria (please visit www.clinicaltrials.gov for more details on eligibility):

1. Male or female and at least 18 years of age.
2. Confirmed newly diagnosed, persistent or recurrent endogenous CS of any etiology, except secondary to malignancy (including pituitary or adrenal carcinoma). Persistence will not be considered confirmed until 6 weeks or more post-surgery.
3. Elevated mean 24 hour UFC levels at least 1.5X ULN of the normative range of the study's central laboratory assay and from a minimum of three measurements from adequately collected urine.
4. Presence of abnormal values from at least one of these two diagnostic tests:
   - Abnormal Dexamethasone Suppression Test (DST): Elevated 8 AM serum cortisol at least 1.8 µg/dL (50 nmol/L) after 1 mg dexamethasone orally at 11 PM the evening prior with concurrent dexamethasone blood concentration greater than 5.6 nmol/liter (0.22 µg/dL) (results from within the 2 months prior to start of Screening or newly tested with results available by the Baseline Visit [TM0]) OR
   - Elevated LNSC concentrations (at least two measurements) each greater than the ULN of the study's central laboratory normative range.

   NOTE: Abnormal LNSC is required among eligible subjects with estimated glomerular filtration rate (eGFR as determined by Modified Diet in Renal Disease MDRD equation) above 40 and below 60 mL/min/1.73 m^2.
5. Non-candidates for CS-specific surgery, refuse surgery or surgery will be delayed for at least 12 months following enrollment and agree to complete this study prior to surgery.
6. If post-surgical for CS-specific surgery, then no significant post operative sequelae remain and the risk of such sequelae is considered negligible.

Subjects with any of the following conditions are excluded from this study (please visit www.clinicaltrials.gov for more details on eligibility):

1. Pseudo-Cushing's syndrome based on assessment of the investigator.
2. Cyclic Cushing's syndrome with multi-week periods of apparent spontaneous CS remission.
3. Non-endogenous source of hypercortisolism, including pharmacological corticosteroids or ACTH.
4. Radiotherapy of any modality directed against the source of hypercortisolism within the last 5 years.
5. Treatment with mitotane within 6 months of enrollment.
6. History of malignancy, including adrenal or pituitary carcinomas (other than low-risk, well-differentiated carcinomas of thyroid, breast or prostate that are very unlikely to require further treatment in the opinion of the treating physician, or squamous cell or basal cell carcinoma of the skin).

LOGICS