Treatment for Endogenous Cushing's Syndrome

Principal Investigator	Peter J. Snyder
Study Title:	Treatment for Endogenous Cushing's Syndrome
Purpose:	The primary objectives of this study are to evaluate the efficacy of ascending doses of COR-003 in subjects with elevated levels of cortisol due to endogenous Cushing's syndrome by assessment of reduction in urinary free cortisol concentrations and to identify the range of safe and effective doses.
Brief Description	This is a single period, open-label, dose titration study to assess efficacy, safety, tolerability and PK of COR-003 in subjects with Cushing's Syndrome. The trial design will identify both the minimally effective and maximally tolerated doses in the CS population. Following an initial screening period, this study will be conducted in 2 treatment phases as follows: Dose titration phase of 2-16 weeks to achieve an effective and tolerable maximum dose. Maintenance phase of 6 months of treatment at the therapeutic dose Extended evaluation phase of 6 months of continued treatment after the maintenance phase.
Eligibility	-18 years and older -confirmed diagnosis of persistent or recurrent Cushings Syndrome or newly diagnosed disease if they are not candidates for surgery -elevated 24 hour urine free cortisol levels > than upper limit of normal based on 4 24 hour urine samples
Compensation (if applicable)	$25 per visit to help cover transportation costs
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