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CLINICAL TRIAL ANNOUNCEMENT

Phase III Trial to Evaluate Relacorilant in Patients with Cushing Syndrome

Official Title: Glucocorticoid Receptor Antagonism in the Treatment of Cushing Syndrome (GRACE): A Phase 3, Double-Blind, Placebo-Controlled, Randomized-Withdrawal Study of the Efficacy and Safety of Relacorilant

The purpose of this study is to evaluate the safety and efficacy of relacorilant for the treatment of endogenous Cushing syndrome with concurrent diabetes mellitus (DM)/impaired glucose tolerance (IGT) and/or uncontrolled hypertension.

Endogenous Cushing syndrome is a rare multisystem disorder resulting from overproduction of the glucocorticoid hormone cortisol. In both adults and children, Cushing syndrome is most commonly caused by an adrenocorticotropic hormone (ACTH)-secreting pituitary tumor (Cushing disease). Other forms of Cushing syndrome result from autonomous production of cortisol from adrenal cortical tumors or overproduction of ACTH from non-pituitary tumors (ectopic ACTH syndrome).

Relacorilant is a potent, selective, glucocorticoid receptor (GR) antagonist and has been shown to be well tolerated in several clinical studies. It has the potential advantage of not having any antiprogesterone effects, including endometrial hypertrophy and the potential for irregular vaginal bleeding.

Key Inclusion Criteria:

- Age 18-80
- Confirmed biochemical diagnosis of endogenous Cushing syndrome
- At least 2 clinical sign/symptoms of Cushing syndrome
- Has one of the following at baseline:
 - DM (fasting plasma glucose ≥ 126 mg/dL and/or 2-hour oGTT plasma glucose ≥ 200 mg/dL) or IGT (plasma glucose ≥ 140 mg/dL and < 200 mg/dL on a 2-hour oGTT)
 - Uncontrolled hypertension (mean SBP ≥ 135 to ≤ 170 mm Hg and/or mean DBP ≥ 85 to ≤ 110 mm Hg)

Key Exclusion Criteria:

- Severe, uncontrolled hypertension (mean SBP > 170 mm Hg or DBP > 110 mm Hg)
- Poorly controlled DM (HbA1c $> 12\%$ at screening)
- Has received pituitary radiation therapy for a Cushing syndrome-related tumor within 1 year of screening