CLINICAL TRIALS

Office based urology trials

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BENIGN PROSTATIC HYPERPLASIA

A MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PARALLEL GROUP STUDY OF THE EFFICACY AND SAFETY OF INTRAPROSTATIC ADMINISTRATION OF BOTOX® 200 U (BOTULINUM TOXIN TYPE A) PURIFIED NEUROTOXIN COMPLEX TO TREAT LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC HYPERPLASIA

Trial ID: 191622-517
Coordination: Allergan
Trial design: A phase II, multicenter, double-blind, randomized, placebo-controlled, parallel-group single-dose study of the efficacy and safety of intraprostatic administration of BOTOX® to treat lower urinary tract symptoms due to benign prostatic hyperplasia. This study has an optional open-label retreatment with BOTOX® 200 U.
Patient population: Male patients 50 years of age and older with a history of lower urinary tract symptoms due to benign prostatic hyperplasia and clinical enlargement of the prostate.
Sample size: n = 274

A DOSE-FINDING, MULTI-CENTRE, DOUBLE-BLIND, RANDOMIZED, PARALLEL, PLACEBO-CONTROLLED TRIAL TO INVESTIGATE EFFICACY AND SAFETY OF DEGARELIX IN MEN WITH LOWER URINARY TRACT SYMPTOMS (LUTS) ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA (BPH)

Trial ID: FE200486
Coordination: CMX Research Inc.
Trial design: This study is designed as a double-blind study to assess safety and efficacy of study drug (degarelix) in male subjects who present with lower urinary tract symptoms in association with BPH.
Patient population: Lower urinary tract symptoms due to benign prostatic hyperplasia.
Sample size: n = 380

PROSTATE CANCER

BONE HEALTH OBSERVATIONAL STUDY

Trial ID: AZ-CMX-03
Coordination: CMX Research Inc.
Trial design: A prospective study to evaluate the incidence of skeletal related events in prostate cancer patients undergoing androgen deprivation therapy (ADT).
Patient population: Male patients undergoing ADT for locally advance prostate cancer.
Sample size: n = 600

ELIGARD® OBSERVATIONAL REGISTRY

Trial ID: ELIGARD® OBSERVATIONAL REGISTRY
Coordination: CMX Research Inc.
Trial design: Long term treatment efficacy, safety and outcome data collection on prostate cancer patients undergoing ADT Therapy with Eligard® utilizing web based database.
Patient population: Male patient with prostate cancer starting ADT with Eligard®.
Sample size: n = 300

SEMEN, PMF AND POST-DRE URINE STUDY

THE IDENTIFICATION OF A DIAGNOSTIC BIOMARKER(S) IN MINIMALLY INVASIVELY COLLECTED SEMEN, PMF AND POST-DRE URINE FOR EARLY SCREENING OF PROSTATE

Trial ID: CUG-004v1
Coordination: CMX Research Inc.
Trial design: This is an epidemiological study analyzing semen, PMF and post-DRE urine samples to identify levels of a genetic biomarker for the purpose of screening and monitoring prostate cancer. Study design is controlled using a test group of samples (diagnosis of prostate malignancy) and a control group of samples (no diagnosis of prostate malignancy).
Patient population: Male patients under the age of 70.
Sample size & endpoint: n = 100

OVERACTIVE BLADDER

A MULTI-CENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PARALLEL GROUP STUDY OF THE SAFETY AND EFFICACY OF A SINGLE TREATMENT OF BOTOX (BOTULINUM TOXIN TYPE A)

Trial ID: 191622-095
Coordination: CMX Research Inc.
Trial design: A multi-center, double-blind, randomized, placebo-controlled, parallel-group study of the safety and efficacy of a single treatment of Botox (Botulinum Toxin Type A). Purified neurotoxin complex followed by a repeat treatment with BOTX as applicable in patients with idiopathic overactive bladder.
Patient population: Patients with symptoms of iOAB with urinary urge incontinence for at least 6 months, whose symptoms have not been adequately managed with anticholinergic therapy.
Sample size & endpoint: n = 546

A PHASE III, RANDOMIZED, DOUBLE-BLIND, PARALLEL GROUP, PLACEBO CONTROLLED, MULTI-CENTER STUDY TO ASSESS THE EFFICACY AND SAFETY OF THE BETA-3 AGONIST YM178 (25 MG AND 50 MG) IN SUBJECTS WITH SYMPTOMS OF OVERACTIVE BLADDER.

Trial ID: 178-CL-074
Coordination: CMX Research Inc.
Trial design: This is a multinational, multicenter, double-blind, randomized parallel group, placebo controlled phase III study. Subjects will be enrolled into a single-blind, 2-week placebo run-in period followed by randomized, double-blind placebo controlled, 12-week treatment period (ratio 1:1:1) There are a total of 6 visits.
Patient population: Outpatient male or female subjects > than or equal to 18 years of age with symptoms of OAB for ≥ 3 months. At baseline subjects have average of ≥ to 8 micturitions per 24 hours and ≥1 urgency episode with or without incontinence per 24 hour period.
Sample size & endpoint: Approximately 1821 enrolled, 1311 randomized, and 1113 evaluable subjects.

PAINFUL BLADDER SYNDROME

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EXPLORE THE EFFICACY, SAFETY, AND TOLERABILITY OF JNJ-42160443 IN SUBJECTS WITH INTERSTITIAL CYSTITIS AND/OR PAINFUL BLADDER SYNDROME

Trial ID: 2160443PAI2005

Coordination: CMX Research Inc.

Trial design: A Phase IIB study to explore the efficacy of JNJ-42160443 compared to placebo using the change in the mean of the average pain intensity at 12 weeks from the baseline pain intensity score, and to assess the safety and tolerability of this treatment in subjects with moderate to severe chronic pain from interstitial cystitis and /or painful bladder syndrome.

Patient population: Men and women aged 18-80 years, inclusive, with moderate to severe, chronic pain from IC and/or PBS.

Sample size & endpoint: n = 70

PREMATURE EJACULATION/ERECTILE DYSFUNCTION

A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, MULTICENTER STUDY OF THE EFFICACY AND SAFETY OF AN SSRI IN MEN WITH PREMATURE EJACULATION AND CONCOMITANT ERECTILE DYSFUNCTION TREATED WITH A PHOSPHODIETERASE-5 INHIBITOR

Trial ID: RO96769-PRE-3008

Coordination: CMX Research Inc.

Trial design: This study is designed to determine the efficacy and safety of a selective serotonin reuptake inhibitor in men with premature ejaculation and erectile dysfunction who are currently receiving stable treatment with a PDE-5 inhibitor for their erectile dysfunction.

Patient population: Male subjects over 18 years of age with co-existing conditions of Erectile dysfunction (ED) and premature ejaculation (PE).

Sample size & endpoint: n = 656