Office based urology trials

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BENIGN PROSTATIC HYPERPLASIA

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

A PHASE II STUDY ASSESSING THE SAFETY AND EFFICACY OF A SINGLE TREATMENT OF 100 U, 200 U, or 300 U BOTOX® COMPARED WITH PLACEBO INJECTED INTO THE PROSTATE TO TREAT LOWER URINARY TRACT SYMPTOMS (LUTS) IN PATIENTS DUE TO BENIGN PROSTATIC HYPERPLASIA

Trial ID: 191622-517-05
Coordination: CMX Research Inc.
Trial design: A phase II study assessing the safety and efficacy of a single treatment of BOTOX® compared with placebo injected into the prostate.
Patient population: Lower urinary tract symptoms due to benign prostatic hyperplasia.
Sample size: n = 300

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: Unlimited

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: 546

A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL GROUP STUDY TO EVALUATE THE EFFICACY AND SAFETY OF TWO DOSES OF DR-3001 VERSUS PLACEBO IN WOMEN WITH OVERACTIVE BLADDER

Trial ID: DR-OXY-301
Coordination: CMX Research Inc.
Trial design: Phase III to evaluate the efficacy and safety of DR-3001 (Oxybutynin Vaginal Ring releasing 4 mg or 6 mg/day) versus placebo over 12 weeks, in women diagnosed with overactive bladder who have symptoms of pure or predominantly urge incontinence, urgency and frequency.
Patient population: 1161
Sample size & endpoint: n = 1548, the primary measure of efficacy will be the change from Visit 1 (Baseline) to Visit 5 (Treatment Week 12/Early Withdrawal) in total weekly number of incontinence episodes.

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.