Office based urology trials

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BENIGN PROSTATIC HYPERPLASIA

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

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE II STUDY OF TRANSPERINEAL INTRAPROSTATIC INJECTION OF PRX302 FOR THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

Trial ID: PRX30222-2-03
Coordination: CMX Research Inc.
Trial design: This study is designed as a randomized, double-blinded, placebo-controlled study of transperineal intraprostatic injection of PRX302, under sonographic guidance in subjects with orate to severe BPH. Subjects will be randomly assigned to one of two treatment groups in ratio of 2:1 between PRX302 and placebo, respectively and stratified by study site age and prostate size.
Patient population: This phase II trial of PRX302 will be conducted in a population of men with moderate to severe BPH.
Sample size: n = 100-120

PROSTATE CANCER

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

12-WEEK, RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER TRIAL TO EVALUATE THE EFFICACY AND SAFEYY OF FESOTERODINE IN COMPARISON TO TOLTERODINE ER IN PATIENT WITH OVERACTIVE BLADDER

Trial ID: AO221046
Coordination: CMX Research Inc.
Trial design: Phase IIIb/IV study to compare the efficacy of fesoterodine with that of placebo and of tolterodine ER in subjects with overactive bladder, after 12 weeks of treatment.
Patient population: Male or female subjects who present with symptoms of OAB.
Sample size: n = 1675

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: Duramed 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.

INTERSTITIAL CYSTITIS

A PHASE II, 12 WEEK, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, PROOF OF CONCEPT STUDY EVALUATING THE EFFICACY AND SAFETY OF PD0299685 FOR THE TREATMENT OF SYMPTOMS ASSOCIATED WITH INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME

Trial ID: A4291043
Coordination: CMX Research Inc.
Trial design: Phase II - proof of concept study to evaluate efficacy and safety of study drug.
Sample size: n = 129