Office based non-oncology urology trials

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BENIGN PROSTATIC HYPERPLASIA

A PHASE III STUDY OF CETRORELIX PAMOATE INTERMITTENT IM DOSAGE REGIMENS IN PATIENTS WITH SYMPTOMATIC BPH: A 1-YEAR PLACEBO-CONTROLLED EFFICACY STUDY AND LONG-TERM SAFETY ASSESSMENT

Trial ID: D-20762-Z033
Coordination: CMX Research
Trial design: To develop a safe and tolerable intermittent dosage regimen of cetrorelix pamoate, that provides prolonged improvement in BPH-related signs and symptoms.
Patient population: Benign prostatic hyperplasia, voiding symptoms: IPSS ≥ 13.
Sample size & endpoint: n = 594, primary endpoint: absolute change in IPSS between baseline (week -1) and week 52. Primary safety endpoint: incidence of treatment-emergent AEs.

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
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

ERECTILE DYSFUNCTION

PIVOTAL PHASE III TRIAL TO INVESTIGATE THE EFFICACY AND SAFETY OF AN ORODISPERSIBLE TABLET VARDENAFIL VERSUS PLACEBO IN THE TREATMENT OF MEN WITH ERECTILE DSYFUNCTION (ED) - A FIXED-DOSE, DOUBLE-BLIND, RANDOMIZED MULTI-CENTER TRIAL N- POTENT 2

Trial ID: 12094
Coordination: CMX Research Inc.
Trial design/treatment: This randomized double-blind, placebo controlled, parallel-arm international, multi-center study will examine the efficacy and safety of BAY 389456 Orodispersible tablet versus placebo in males 18 years and older with erectile dysfunction.
Patient population: Male subject 18 years of age and older and have a clinical diagnosis of ED and who meet eligibility criteria.
Sample size: n = 280

OVERACTIVE BLADDER

A DOUBLE-BLIND, RANDOMIZED, PARALLEL, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE EFFECT OF TREATMENT WITH TOPICALLY ADMINISTERED OXYBUTYNIN GEL IN PATIENTS WITH URINARY FREQUENCY, AND URGE AND MIXED URINARY INCONTINENCE WITH A PREDOMINANCE OF URGE INCONTINENCE EPISODES

Trial ID: 20070060
Coordination: CMX Research
Trial design: To evaluate the effects of oxybutynin gel (at doses of 56 mg oxybutynin/day and 84 mg oxybutynin/day), relative to placebo in patients with urge and mixed urinary incontinence with a predominance of urge incontinence on:
Patient population: Patients with urge and/or mixed urinary incontinence with a predominance of urge incontinence episodes (at least 2:1 urge to stress incontinence episodes).
Sample size & endpoint: n = 600, the change from baseline to week 12 in the number of urinary incontinence episodes (UIE) per week, as determined from a 3-day patient daily diary.

RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP STUDY OF VARDENAFIL 10 MG TWICE DAILY TO ASSESS THE EFFECT ON URODYNAMICS IN PATIENTS WITH OVERACTIVE BLADDER (DETRUSOR OVERACTIVITY)

Trial ID: BAY-38-9456
Coordination: CMX Research
Trial design: To determine the therapeutic effect of vardenafil 10 mg taken twice daily (BID) on overactive bladder by means of urodynamic measurements (filling cystometry and pressure flow investigations).
Patient population: Subjects with overactive bladder (with or without urge incontinence) for at least 6 months. Forty percent subjects recruited should be male.
Sample size & endpoint: n = 481, change from baseline in bladder volume at first detrusor contraction. Change in the number of daily micturition as reported in the patient diaries.

A RANDOMIZED, DOUBLE-BLIND, PARALLEL GROUP, ACTIVE CONTROLLED, MULTICENTER LONG-TERM STUDY TO ASSESS THE SAFETY AND EFFICACY OF THE BETA-3 AGONIST YM178 (50 MG QD AND 100 MG QD) IN SUBJECTS WITH SYMPTOMS OF OVERACTIVE BLADDER

Trial ID: YM178-CL-049
Coordination: CMX Research
Trial design: To assess the safety and tolerability of long-term treatment with YM178 (50 mg qd and 100 mg qd) in subjects with symptoms of overactive bladder.
Patient population: The study will randomize female and male subjects at least 18 years of age, who have symptoms of overactive bladder (urinary frequency and urgency with or without incontinence for at least 3 months).
Sample size & endpoint: n = 2500, approximately 2500 subjects will be enrolled. This number is not based on a formal sample size calculation. Primarily, subjects who completed the pivotal studies (178-CL-046 or 178-CL-047) will be enrolled. However, subjects not participating in these studies may be enrolled as well.

THE EFFECTS OF INTRAVESICAL INJECTION OF BOTOX® ON PATIENTS WITH URINARY URGENCY AND FREQUENCY WITHOUT INCONTINENCE DUE TO OVERACTIVE BLADDER

Trial ID: ALG-CMX-01
Coordination: CMX Research
Trial design: The study proposes to examine the efficacy of Botox® in dry OAB patients by using standard voiding diaries and quality of life (QOL) questionnaires. In addition, safety and the duration of the clinical response will be monitored.
Patient population: Urinary frequency and urgency without incontinence.
Sample size & endpoint: n = 20, the primary endpoint is the number of urinary urgency episodes per day as recorded in a 3-day bladder diary at 3 months.

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 IIIb STUDY COMPARING THE EFFICACY OF FESOTERODINE TO PLACEBO AND TOLTERODINE ER IN SUBJECTS WITH OVERACTIVE BLADDER AFTER 12 WEEKS OF TREATMENT

Trial ID: A0221008
Coordination: CMX Research
Trial design: A 12-week, randomized, double-blind, double-dummy, placebo-controlled, parallel-group, multicenter trial to evaluate the efficacy and safety of fesoterodine in comparison to tolterodine ER in patients with overactive bladder.
Patient population: Overactive bladder with symptoms of frequency, urgency, and urgency incontinence.
Sample size & endpoint: n = 1675, primary endpoint: change in mean number of urgency urinary incontinence (UUI) episodes per 24 hours at week 12 relative to the baseline.

A PHASE II STUDY TO ASSESS THE EFFICACY AND SAFETY OF MODIFIED RELEASE UK-369,003 IN THE TREATMENT OF MEN WITH STORAGE LOWER URINARY TRACT SYMPTOMS (LUTS) WITH AND WITHOUT ERECTILE DYSFUNCTION (ED).

Trial ID: A3711047
Coordination: CMX Research
Trial design: A multi-national, multi-center, double-blind, randomized, placebo-controlled, parallel group phase II study with five treatment arms.
Patient population: Male aged 18 and above, with documented clinical diagnosis of OAB, with mean urinary frequency ≥ 8 times/24 hours, and mean number of urgency episodes with or without urgency incontinence ≥1 episode/24 hours.
Sample size & endpoint: n = 300, efficacy endpoints based on: LUTS diary scores, International Prostate Symptom Score, Overactive Bladder questionnaire, Patient Perception of Bladder Condition, International Consultation on Incontinence Questionnaire, Erectile Function domain of International Index of Erectile Function, Quality of Erection questionnaire, Patient Reported Treatment Impact questionnaire, Population Pharmacokinetics.

INTERSTITIAL CYSTITIS

A MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL GROUP EVALUATION OF THE EFFICACY AND SAFETY OF URACYST® (INTRAVESICAL SODIUM CHONDROITIN SULFATE) VERSUS VEHICLE PLACEBO IN PATIENTS WITH INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME (IC/PBS)

Trial ID: UR07001
Coordination: CMX Research
Trial design: Prospective, randomized, double-blind, vehicle placebo-controlled, 12-week study, including a 6-week treatment period, followed by a 6-week follow-up period.
Patient population: Male and females at least 18 years of age and have a clinical diagnosis of IC/PBS and who meet eligibility criteria.
Sample size: n = 50

A PLACEBO CONTROLLED RANDOMIZED, 12-WEEK, DOSE-RANGING, DOUBLE-BLIND STUDY VERSUS PLACEBO USING TOLTERODINE AS A STUDY CALIBRATOR, TO EVALUATE EFFICACY AND SAFETY OF SSR240600C IN WOMEN WITH OVERACTIVE BLADDER INCLUDING URGE URINARY INCONTINENCE

Trial ID: DRI6271
Coordination: CMX Research
Trial design: A multi-center randomized, double-blind, 5-arm, parallel group study comparing three doses of SSR240600 (25, 50, and 100 mg) to placebo using tolterodine as a calibrator. The study consists of 3 phases: a) screening period of 1 week, b) double-blind treatment period of 12 weeks, and c) follow-up period of 2 weeks.
Patient population: Females ≥ 18 and ≤ 70 years of age with diagnosis of overactive bladder with symptoms of urgency with urge incontinence and frequency (≥ 1 urgency episode per day, ≥ 8 micturitions per day, ≥ 5 urge urinary incontinence (UUI) episodes/week), which may be associated with nocturia, but without bladder pain.
Sample size: n = 800

PREMATURE EJACULATION

A PHASE IIb, MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY, WITH OPEN-LABEL FOLLOW ON, TO EVALUATE THE EFFICACY, SAFETY AND TOLERABILITY OF PSD502 IN SUBJECTS WITH PREMATURE EJACULATION (PE)

Trial ID: PSD502-PE-002
Coordination: CMX Research
Trial Design: Phase IIb, multi-center, randomized, double-blind, placebo-controlled study. Subjects will be randomized to PSD502 or placebo in a 2:1 ratio.
Patient Population: Male subjects with PE according to Diagnostic and Statistical Manual of Mental Disorders (DSM IV) criteria, aged 18 and over.
Sample Size: n = 240-300