

## *Office based urology trials*

Richard W. Casey, MD,<sup>1</sup> Jack Barkin, MD<sup>2</sup>

<sup>1</sup>The Male Health Centre, Oakville, Ontario, Canada

<sup>2</sup>Humber River Regional Hospital, University of Toronto, Toronto, Ontario, Canada

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### **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:** n = 300

#### DELAY- DEGARELIX PHASE IV

**Trial ID:** DELAY 2010  
**Coordination:** CMX Research Inc  
**Trial design:** Phase IV observational long term efficacy, safety and outcome data collection on prostate cancer patients undergoing Degarelix treatment after failing previous ADT agents.  
**Patient population:** Male patients with prostate cancer starting Degarelix after failing previous ADT therapy.  
**Sample size:** n = 75

#### A PHASE III, RANDOMIZED, DOUBLE-BLIND, MULTICENTER TRIAL COMPARING ORTERONEL (TAK-700) PLUS PREDNISONE WITH PLACEBO PLUS PREDNISONE IN PATIENTS WITH CHEMOTHERAPY-NAÏVE METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

**Trial ID:** C21004  
**Coordination:** CMX Research Inc.  
**Trial design:** This is a randomized, double-blind, multicenter, phase III study evaluating orteronel plus prednisone compared with placebo plus prednisone in the treatment of men with progressive, chemotherapy-naïve, metastatic, castration-resistant prostate cancer (mCRPC). Patients in the two treatment groups will receive blinded orteronel (or placebo) in addition to open-label prednisone and gonadotropin-releasing hormone (GnRH) analogue therapy.  
**Patient population:** Men at least 18 years of age who have histologically or cytologically confirmed adenocarcinoma of the prostate and documented progressive metastatic disease, based on either radiographic or PSA criteria, despite castrate levels of testosterone (< 50 ng/dL).  
**Sample size:** n = 1454

A PHASE III, RANDOMIZED, DOUBLE-BLIND, MULTICENTER TRIAL COMPARING ORTERONEL (TAK-700) PLUS PREDNISONE WITH PLACEBO PLUS PREDNISONE IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER THAT HAS PROGRESSED DURING OR FOLLOWING DOCETAXEL-BASED THERAPY

**Trial ID:** C21005  
**Coordination:** CMX Research Inc.  
**Trial design:** This is a randomized, double-blind, multicenter, phase III study evaluating orteronel plus prednisone, compared with placebo plus prednisone, in men with metastatic, castration-resistant prostate cancer (mCRPC). Gonadotropin-releasing hormone (GnRH) analogue therapy will be continued unless the patient is surgically castrate.  
**Patient population:** Men at least 18 years of age who have histologically confirmed or cytologically confirmed adenocarcinoma of the prostate that has progressed following 1 to 2 prior cytotoxic chemotherapies, at least 1 of which must have included docetaxel therapy. Patients can be symptomatic or asymptomatic.  
**Sample size:** n = 1083

A DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE NEW OR WORSENING LENS OPACIFICATIONS IN SUBJECTS WITH NON-METASTATIC PROSTATE CANCER RECEIVING DENOSUMAB FOR BONE LOSS DUE TO ANDROGEN-DEPRIVATION THERAPY

**Trial ID:** 20080560  
**Coordination:** CMX Research Inc.  
**Trial design:** This is a multi-center, randomized, double-blind, placebo-controlled study in patients with non-metastatic prostate cancer undergoing androgen deprivation therapy (ADT). Approximately 760 patients will be randomly assigned to receive placebo or denosumab at a dose of 60 mg once every 6 months (Q6M) in a 1:1 allocation ratio for 12 months (i.e. study day 1 and month 6).  
**Patient population:** Patients with baseline LOCS III status (< 3.0 at all sites [P,C,NO] vs. ≥ 3.0 at any of these sites), age group (< 70, 70 to 80 years, > 80 years), and subject-reported history of cataract (yes/no).  
**Sample size:** n = 760

AN OPEN-LABEL, MULTI-CENTRE, RANDOMIZED, PARALLEL-ARM ONE-YEAR TRIAL, COMPARING THE EFFICACY AND SAFETY OF DEGARELIX THREE-MONTH DOSING REGIMEN WITH GOSERELIN ACETATE IN PATIENTS WITH PROSTATE CANCER REQUIRING ANDROGEN DEPRIVATION THERAPY

**Trial ID:** 200486 C35  
**Coordination:** CMX Research Inc.  
**Trial design:** This is an open-label, multi-centre, randomized, parallel-arm trial with subcutaneous (s.c.) injections of degarelix three-month depot or goserelin acetate three-month implant in patients with advanced prostate cancer.  
**Patient population:** Male patients 18 years or older. Patients with histologically confirmed adenocarcinoma of the prostate for which endocrine treatment is indicated.  
**Sample size:** n = 825

## ***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:** 200486 CS36  
**Coordination:** CMX Research Inc.  
**Trial design:** 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.  
**Patient population:** Male patients, aged 50 or older. Clinical signs and symptoms of BPH for greater than 6 months. Moderate to severe LUTS at screening, as defined by IPSS greater than 13. An IPSS QoL score of greater than 3 at screening. Prostate specific antigen (PSA) at screening less than 10 ng/mL. Maximum urinary flow (Qmax) ranging between 5 to 15 mL/second with a minimum voided greater than 125 mL at screening.  
**Sample size & endpoint:** n = 128

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:** 191622-100  
**Coordination:** CMX Research Inc.  
**Trial design:** This is a multicenter, double-blind, randomized, placebo-controlled, parallel-group, single-dose study; with the option of open-label retreatment with BOTOX® 200 U. The study will assess the efficacy of intraprostatic administration of BOTOX® 200 U compared with placebo to treat lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).  
**Patient population:** Men with a history of LUTS and signs suggestive of BPH with clinical enlargement of the prostate, who have previously been treated with licensed oral BPH pharmacotherapy or who do not wish to continue on their current BPH pharmacotherapy, and who have not had a marked response following the sham run-in period.  
**Sample size & endpoint:** n = 274

## ***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

***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 PHOSPHODIESTERASE-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