CHOA Clinical Trial Master List

PROSTATE

USO# 16160 – CO39303- A Phase III, Randomized, double-blind, placebo-controlled, multi-center trial, testing Ipatasertib plus Zytiga plus Prednisone/Prednisolone, relative to placebo plus Zytiga plus Prednisone/Prednisolone inpatients with asymptomatic or mildly symptomatic metastatic castrate-resistant prostate cancer with PTEN-LOSS (PTEN diagnostic positive) tumors	
Sponsor: Roche ****Must be able to provide tissue block or slides to Central Lab for Inclusion Criteria**** ****Prior Provenge treatment is exclusionary**** ****Assistance with Zytiga co-pay provided by sponsor****	Therapy Line: **1st Line after hormone therapy progression** Drug Classification: **AKT inhibitor which results in the inhibition of the PI3K/AKT pathway**
Principal Investigator: David M. Ellison, MD	**CRC:** Stephanie Patel, ext. 212

Basic Enrollment Information: Inclusion Criteria: ECOG 0 or 1; Life expectancy of at least 6 months; Histologically confirmed prostate adenocarcinoma without neuroendocrine differentiation or small-cell features; Consent to provide a formalin-fixed paraffin-embedded (FFPE) tissue block(preferred) or a minimum of 15 (20 preferred) freshly cut unstained tumor slides from the most recently collected, **available tumor tissue accompanied by an associated pathology report (with tumor content information, Gleason score, and disease staging) for PTEN IHC and NGS testing and for other protocol-mandated secondary and exploratory assessments**. Cytologic or fine-needle aspiration samples are not acceptable. Tumor tissue from bone metastases that is subject to decalcification is not acceptable. **A valid PTEN IHC result (per central testing).** Metastatic disease documented prior to randomization by bone lesions on bone scan or soft tissue disease by CT or MRI. **Ongoing androgen deprivation with gonadotropin-releasing hormone (GnRH) analog or bilateral orchiectomy, with serum testosterone < 50 ng/dL (< 2.0 nmol/L) within 28 days before randomization; previous treatment with bicalutamide, flutamide, and nilutamide is permitted.** Patients whose PSA did not decline for ≥ 3 months in response to an anti-androgen given as a second-line or subsequent intervention will require only a 2-week washout before Day 1 is permitted

Exclusion Criteria: No prior anti-cancer therapy; Enzalutamide or other potent androgen-receptor blockers, approved or experimental (e.g., ARN-509, ODM-201, or galeterone) Prior treatment with bicalutamide (Casodex®) or nilutamide (Nilandron®) within 6 weeks of Cycle 1, Day 1. Inability or unwillingness to swallow whole pills; History of malabsorption syndrome or other condition that would interfere with enteral absorption. Clinically significant history of liver disease consistent with Child-Pugh Class B or C, including cirrhosis, current alcohol abuse, or current known active infection with hepatitis B virus (HBV) or hepatitis C virus (HCV). Active infection requiring intravenous (IV) antibiotics within 14 days before Day 1,Cycle 1. Immunocompromised status because of current known active infection with HIV or because of the use of immunosuppressive therapies for other conditions. History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias, such as structural heart disease (e.g., severe left ventricular systolic dysfunction, left ventricular hypertrophy), coronary heart disease (symptomatic or with ischemia demonstrated by diagnostic testing), myocardial infarction or atrial thrombotic events within the past 6 months, severe unstable angina, New York Heart Association Class III and IV heart disease or depressed left ventricular ejection fraction (LVEF; < 50%), clinically significant electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia, hypocalcemia), or family history of sudden unexplained death or long QT syndrome. History of other malignancy within the previous 5 years, except for appropriately treated non-melanoma skin carcinoma, or patients who have undergone potentially curative therapy with no evidence of disease and are deemed by the treating physician to be at low risk for recurrence. Any prior anti-cancer therapy. Known untreated or active central nervous system (CNS) metastases (progressing or requiring anticonvulsant medications or corticosteroids for symptomatic control); a CT or MRI scan of the brain will be performed at screening if required by the local health authority.

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