# Available Trial - Intermittent Androgen Deprivation Therapy plus Ipilumimab (Yervoy) for Men with Metastatic Hormone Sensitive Prostate Cancer

A Phase II Study of Ipilimumab plus Androgen Deprivation Therapy in Castrate Sensitive Prostate Carcinoma

## Objective:

- To estimate the rate of PSA </= 0.2ng/mL at 7 months in patients treated with androgen deprivation therapy (ADT) plus Ipilimumab
- To determine the overall survival of patients treated with intermittent ADT and ipilimumab

## Patients may be Eligible:

- Histologically or cytologically confirmed prostate carcinoma
- Evidence of metastatic disease on bone and/or CT and/or MRI scan
- **Castrate-sensitive disease: Eligible up to 1 month from LHRH analog or antagonist injection**
- Adequate organ function and performance status
- No prior orchiectomy
- No history of autoimmune disorder, HIV, Hepatitis B or Hepatitis C
- Not eligible with Small cell carcinoma of the prostate
- No brain metastases or untreated symptomatic spinal cord compressions
- Not received any vaccine for prevention of infectious diseases within a month
- No concomitant therapy with immunomodulatory drugs such as interferon or chronic systemic steroids.

## Procedure:

- Imaging studies are required within 28 days of study entry
- During the first 8 months of study monthly visits to MD Anderson with laboratory studies are required
- After month 8, visits to MD Anderson with laboratory studies are required every 3 months
- Interim diagnostic imaging is only performed if disease progression is suspected
- Diagnostic imaging is required at the off-study evaluation
- Patients are asked to give an additional 6 tablespoons of blood for correlative laboratory studies as an optional procedure

## Benefit for Patients:

- May result in an improved and more durable response to androgen deprivation therapy
- May result in a decrease in the amount of time patients are subject to castration

## Protocol 2009-0378

**IRB approved 10/07/2011**


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- Schedule an appointment or make referral online at https://my.mdanderson.org or call (713) 745-7020 or 1-866-363-1332
- For more information about the study, contact Cherie Perez, Quality Assurance Specialist, GU Medical Oncology, at (713) 563 -1602 or caperez@mdanderson.org


- For information on related articles or references for this study, visit http://physicianrelations.org
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