

The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2020-4410
Date:	28 August 2020
Product Name:	Abiraterone acetate
Therapeutic Area:	Oncology
Product Class:	CYP17 inhibitor
Condition(s) Studied:	Prostate Cancer
Protocol Number(s) and Title(s):	<p>NCT02236637 - 212082PCR4001- A Prospective Registry of Patients With a Confirmed Diagnosis of Adenocarcinoma of the Prostate Presenting With Metastatic Castrate-Resistant Prostate Cancer</p> <p>NCT01695135- ABI-PRO-3001- A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Docetaxel-Based Chemotherapy</p> <p>NCT01867710- 212082PCR2023- A Randomized Phase 2 Study Evaluating Abiraterone Acetate With Different Steroid Regimens for Preventing Symptoms Associated With Mineralocorticoid Excess in Asymptomatic, Chemotherapy-naïve and Metastatic Castration-resistant Prostate Cancer (mCRPC) Patients</p> <p>NCT00638690-COU-AA-301 A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Docetaxel-Based Chemotherapy</p> <p>NCT00887198-COU-AA-302 A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer</p> <p>NCT01715285 212082PCR3011 A Randomized, Double-blind, Comparative Study of Abiraterone Acetate Plus Low-Dose Prednisone Plus Androgen Deprivation Therapy (ADT) Versus ADT Alone in Newly Diagnosed Subjects With High-Risk, Metastatic Hormone-naive Prostate Cancer (mHNPC)</p>
Part 2: Data Availability	
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes
Comments:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes

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Comments:		
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).		Yes
Comments:		
Part 3: Data Availability Summary		
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.		Yes
Part 4: Proposal Review		
Question:		Response:
Summary-level CSR data is appropriate for the proposed analysis.		Yes
Participant-level data is appropriate for the proposed analysis.		Yes
A similar analysis is underway or completed/pending disclosure by Janssen.		No
Comments:		