

## The YODA Project Research Proposal Due Diligence Assessment

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2022-5106
<b>Date:</b>	7 February 2023
<b>Product Name:</b>	Abiraterone acetate
<b>Therapeutic Area:</b>	Oncology
<b>Product Class:</b>	Hormones
<b>Condition(s) Studied:</b>	Prostate Cancer
<b>Protocol Number(s) and Title(s):</b>	<p><b>NCT00638690 - COU-AA-301</b> - 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><b>NCT00887198 - COU-AA-302</b> - 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><b>NCT01695135 - ABI-PRO-3001</b> - 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><b>NCT02236637 - 212082PCR4001</b> - A Prospective Registry of Patients With a Confirmed Diagnosis of Adenocarcinoma of the Prostate Presenting With Metastatic Castrate-Resistant Prostate Cancer</p> <p><b>NCT01795703 - JNJ-212082-JPN-202</b> - A Phase II Study of JNJ-212082 (Abiraterone Acetate) in Metastatic Castration-Resistant Prostate Cancer Patients Who Have Received Docetaxel-based Chemotherapy</p> <p><b>NCT01867710 - 212082PCR2023</b> - 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><b>NCT01715285 - 212082PCR3011</b> - 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> <p><b>NCT01591122 - ABI-PRO-3002</b> - A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (JNJ-212082) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer</p> <p><b>NCT02257736 - 56021927PCR3001</b> - A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects With Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)</p>

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<b>Part 2: Data Availability</b>	
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
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:	
<b>Part 3: Data Availability Summary</b>	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes
<b>Part 4: Proposal Review</b>	
Question:	Response:
Summary-level CSR data is appropriate for the proposed analysis.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	