

## The YODA Project

### Research Proposal Due Diligence Assessment

<b>Part 1: General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2024 – 0360
<b>Date:</b>	March 22, 2024
<b>Product Name:</b>	Zytiga
<b>Therapeutic Area:</b>	Oncology
<b>Product Class:</b>	Androgen biosynthesis inhibitors
<b>Condition(s) Studied:</b>	Prostate Neoplasms
<b>Protocol Number(s) and Title(s):</b>	<ol style="list-style-type: none"> <li>1. <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)</li> <li>2. <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</li> <li>3. <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</li> </ol>
<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>	

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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>	
<b>Question:</b>	<b>Response:</b>
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:	