## Part 1: General Information

<table>
<thead>
<tr>
<th>YODA Project ( Protocol) ID:</th>
<th>2024 – 0060</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td>January 22, 2024</td>
</tr>
<tr>
<td>Product Name:</td>
<td>Abiraterone acetate/Canagliflozin/Paliperidone</td>
</tr>
<tr>
<td>Therapeutic Area:</td>
<td>Oncology/CVM/Neuroscience</td>
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<tr>
<td>Product Class:</td>
<td>Androgen biosynthesis inhibitors/Sodium-glucose co-transporter 2 inhibitors/Atypical antipsychotics</td>
</tr>
<tr>
<td>Condition(s) Studied:</td>
<td>Prostate Neoplasms/Diabetes/Schizophrenia</td>
</tr>
</tbody>
</table>
| Protocol Number(s) and Title(s): | 1. 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  
2. 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  
3. 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)  
4. NCT02236637 - 212082PCR4001: A Prospective Registry of Patients With a Confirmed Diagnosis of Adenocarcinoma of the Prostate Presenting With Metastatic Castrate-Resistant Prostate Cancer  
5. NCT02065791 - 28431754DNE3001: A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy  
6. NCT01989754 - 28431754DIA4003: A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus  
7. NCT01032629 - 28431754DIA3008: A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of JNJ-28431754 on Cardiovascular Outcomes in Adult Subjects With Type 2 Diabetes Mellitus  
8. NCT01809327 - 28431754DIA3011: A Randomized, Double-Blind, 5-Arm, Parallel-Group, 26-Week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in Combination With Metformin as Initial Combination Therapy in the Treatment of Subjects With Type 2 Diabetes |
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Research Proposal Due Diligence Assessment

Mellitus With Inadequate Glycemic Control With Diet and Exercise

9. NCT00968812 - A Randomized, Double-Blind, 3-Arm Parallel-Group, 2-Year (104-Week), Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-28431754 Compared With Glimepiride in the Treatment of Subjects With Type 2 Diabetes Mellitus Not Optimally Controlled on Metformin Monotherapy

10. NCT01106677 - A Randomized, Double-Blind, Placebo and Active-Controlled, 4-Arm, Parallel Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Monotherapy

11. NCT00460512 - An Open-label Prospective Trial to Explore the Tolerability, Safety and Efficacy of Flexibly Dosed Paliperidone ER in Subjects With Schizophrenia

12. NCT00589914 - A Randomized, Double-Blind, Parallel-Group, Comparative Study of Flexible Doses of Paliperidone Palmitate and Flexible Doses of Risperidone Long-Acting Intramuscular Injection in Subjects With Schizophrenia

13. NCT01281527 - A 6-month, Open Label, Prospective, Multicenter, International, Exploratory Study of a Transition to Flexibly Dosed Paliperidone Palmitate in Patients With Schizophrenia Previously Unsuccessfully Treated With Oral or Long-acting Injectable Antipsychotics

14. NCT01515423 - A Randomized, Multicenter, Double-Blind, Non-inferiority Study of Paliperidone Palmitate 3 Month and 1 Month Formulations for the Treatment of Subjects With Schizophrenia

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

Comments: 
The YODA Project  
Research Proposal Due Diligence Assessment

| 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

<table>
<thead>
<tr>
<th>Question:</th>
<th>Response:</th>
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<tbody>
<tr>
<td>Summary-level CSR data is appropriate for the proposed analysis.</td>
<td>No</td>
</tr>
<tr>
<td>Participant-level data is appropriate for the proposed analysis.</td>
<td>Yes</td>
</tr>
<tr>
<td>A similar analysis is underway or completed/pending disclosure by Janssen.</td>
<td>No</td>
</tr>
<tr>
<td>Comments: Some work is/has been done on virtual comparator arms but NOT for rare diseases</td>
<td></td>
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