Due Diligence Assessment – Research Proposal

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4836
Date:	14 September 2021_updated_30Mar22
Product Name:	Galantamine/Abiraterone Acetate
Therapeutic Area:	Neuroscience
Product Class:	AZ Disease - Cholinesterase Inhibitors
Condition(s) Studied:	Alzheimer Disease/ Prostate Cancer
Protocol Number(s) and Title(s):	**GAL-INT-3** - Long Term Safety and Efficacy of Galantamine in the treatment of Alzheimer's Disease **NCT00253201 - GAL-USA-1** - Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease **NCT00253227 - GAL-INT-2** - Galantamine in the Treatment of Alzheimer's Disease: Flexible Dose Range Trial **NCT00216502 - GAL ITA-2** - Long Term Treatment With Galantamine In Dementia **NCT00253188 - GAL-INT-1** - Efficacy, Tolerability and Safety of Galantamine in the Treatment of Alzheimer's Disease **NCT00253214 - GAL-INT-10** - Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation **NCT00236431 - GAL-INT-18** - A Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Patients With Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease **NCT00679627 - GALALZ3005** - A Randomized, Double-Blind, Placebo-controlled Trial of Long-term (2-year) Treatment of Galantamine in Mild to Moderately-Severe Alzheimer's Disease **NCT00216593 - GAL-ALZ-302** (PMID # 19042161-CR003940) - Treatment of Severe Alzheimer's Disease in a Residential Home, Nursing Home, or Geriatric Residential Setting: Evaluation of Efficacy and Safety of Galantamine Hydrobromide in a Randomised, Doubleblind, Placebo-Controlled Study **NCT00645190 - GAL-CHN-T100** - A Randomized, Double Blind, Active Control, Flexible Dose, Multicenter Study to Evaluate Galantamine HBr in the Treatment of Alzheimer's Disease:Safety and Effectiveness of an Immediate-release Table Formulation. **NCT00261573 - GAL-INT-6** - The Safety and Efficacy of Galantamine in the Treatment of Vascular and Mixed Dementia **NCT00236574 - GAL-INT-11** - A Randomized Double Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Galantamine in Patients With Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease **GAL-USA-10** - Placebo-controlled evaluation of galantamine in the treatment of Alzheimer’s disease: Evaluation of safety and efficacy under a slow titration regimen
Part 2: Data Availability	

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Question:	Response:
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments: N/A	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A	
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: N/A	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments: N/A	
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: N/A	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	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.	No
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	