The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4683
Date:	12 August 2021
Product Name:	Galantamine/Bapineuzumab/Risperidone/Topiramate
Therapeutic Area:	Neuroscience
Product Class:	AZ Disease - Cholinesterase Inhibitors/ Monoclonal Antibody/ Anticonvulsants
Condition(s) Studied:	Alzheimer Disease/Migraine/Dementia
Protocol Number(s) and Title(s):	**1. NCT00236561 - TOPMAT-MIGR-003 -** A Randomized, Double-Blind, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of Two Doses of Topiramate Compared to Placebo and Propranolol in the Prophylaxis of Migraine **2. NCT00210912 - CAPSS-276 -** A Comparison of the Efficacy and Safety of Topiramate Versus Placebo for the Prophylaxis of Chronic Migraine **3. NCT00249158 - RIS-AUS-5 -** Risperidone in the Treatment of Behavioural and Psychological Signs and Symptoms in Dementia (BPSSD): a Multicentre, Double-blind, Placebo-controlled Parallel-group Trial **4. NCT00034762 - RIS-USA-232 -** Efficacy And Safety Of A Flexible Dose Of Risperidone Versus Placebo In The Treatment Of Psychosis Of Alzheimer's Disease **NCT00253123 - RIS-USA-63 -** A Randomized, Double-Blind, Placebo-Controlled Study of Risperidone for Treatment of Behavioral Disturbances in Subjects With Dementia **6. NCT00253214 - GAL-INT-10 -** Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation **7. 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 **8. 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 **9. 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 **10. NCT00216619 - TOPMAT-MIG-303 -** A Double-Blind, andomized, Placebo-Controlled, Multicenter Trial to Investigate the Efficacy and Tolerability of Topiramate in Prolonged Migraine Prevention **11. 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 **12. NCT00575055 - ELN115727-302 -** A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group,

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	Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) In Patients With Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein E4 Carriers **13. NCT00574132 - ELN115727-301 -** A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) In Patients With Mild to Moderate Alzheimer's Disease Who Are Apolipoprotein E4 Non- Carriers

Part 2: Data Availability

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.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	