

The YODA Project

Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2020-4323
Date:	21 Jul 2020
Product Name:	Galantamine/Bapineuzumab
Therapeutic Area:	Neuroscience
Product Class:	AZ Disease - Cholinesterase Inhibitors/ Monoclonal Antibody
Condition(s) Studied:	Alzheimer Disease
Protocol Number(s) and Title(s):	<p>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</p> <p>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</p> <p>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</p> <p>NCT00253214 GAL-INT-10 Placebo-Controlled Evaluation of Galantamine in the Treatment of Alzheimer's Disease: Safety and Efficacy of a Controlled-Release Formulation</p> <p>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</p> <p>NCT00216593 GAL-ALZ-302- 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</p> <p>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</p> <p>NCT00575055 - ELN115727-302 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 Carriers</p>
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	

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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.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	