The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4568
Date:	18 February 2021
Product Name:	Risperidone/ Paliperidone
Therapeutic Area:	Neuroscience
Product Class:	Atypical antipsychotics
Condition(s) Studied:	Schizophrenia
Protocol Number(s) and Title(s):	**Paliperidone:** **NCT00334126** - **R076477SCH3015** - A Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Paliperidone ER Compared to Quetiapine in Subjects With an Acute Exacerbation of Schizophrenia **NCT00650793 - R076477-SCH-703** - A Randomized, DB, PC and AC, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Extended Release OROS Paliperidone (6, 9, 12 mg/Day) and Olanzapine (10 mg/Day), With Open-Label Extension, in the Treatment of Subjects With Schizophrenia - Open Label Phase **NCT00590577 - R092670PSY3007** - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia **NCT00210548 - R092670PSY3003** - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia **NCT00101634 - R092670PSY3004** - A Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (25 mg eq, 50 mg eq, and 100 mg eq) of Paliperidone Palmitate in Patients With Schizophrenia **NCT00397033 - R076477SCA3001** - A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Two Dosages of Paliperidone ER in the Treatment of Patients With Schizoaffective Disorder **NCT00412373 - R076477SCA3002** - A Randomized, Double-blind, Placebo-controlled, Parallel- Group Study to Evaluate the Efficacy and Safety of Flexible-dose Paliperidone ER in the Treatment of Patients With Schizoaffective Disorder **NCT00083668 - R076477-SCH-305** - A Randomized, Double-blind, Placebo- and Active-controlled, Parallelgroup, Dose-response Study to Evaluate the Efficacy and Safety of 3 Fixed Dosages of Paliperidone Extended Release (ER) Tablets and Olanzapine, With Open-label Extension, in the Treatment of Patients With Schizophrenia 10. **NCT00074477 - R092670-SCH-201** - A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50

	and 100 Mg-eq of Paliperidone Palmitate in Patients With Schizophrenia **NCT00078039 - R076477-SCH-303** - Trial Evaluating Three Fixed Dosages of Paliperidone ExtendedRelease (ER) Tablets and Olanzapine in the Treatment of Patients With Schizophrenia 12. **NCT00085748 - R076477-SCH-302** - A Randomized, 6-Week Double-Blind, Placebo-Controlled Study With an Optional 24-Week Open-Label Extension to Evaluate the Safety and Tolerability of Flexible Doses of Paliperidone Extended Release in the Treatment of Geriatric Patients With Schizophrenia **NCT00524043 - R076477SCH4012** - A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of a Fixed Dosage of 1.5 mg/Day of Paliperidone Extended Release (ER) in the Treatment of Subjects With Schizophrenia **NCT01299389 - PALM-JPN-4** - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, FixedDose, Multicenter Study of JNS010 (Paliperidone Palmitate) in Patients With Schizophrenia **Risperidone:** **NCT00249132 - RIS-INT-3** - A Canadian multicenter placebo-controlled study of fixed doses of risperidone and haloperidol in the treatment of chronic schizophrenic patients **NCT00253136 - RIS-USA-121** - Risperidone Depot (Microspheres) vs. Placebo in the Treatment of Subjects With Schizophrenia

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

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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:	