The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2023 – 5502
Date:	February 7, 2024
Product Name:	Daratumumab/Risperidone/Paliperidone Palmitate/Etravirine/Ibrutinib/Macitentan
Therapeutic Area:	Oncology/Neuroscience/IDV/PH
Product Class:	Monoclonal antibodies/atypical antipsychotics/non-nucleoside reverse transcriptase inhibitors/kinase inhibitors/endothelin receptor antagonists
Condition(s) Studied:	Multiple Myeloma/ Schizophrenia/HIV/Graft Versus Host Disease/
Protocol Number(s) and Title(s):	1. **NCT01998971 - 54767414MMY1001**: An Open-Label, Multicenter, Phase 1b Study of JNJ-54767414 (HuMax CD38) (Anti-CD38 Monoclonal Antibody) in Combination With Backbone Regimens for the Treatment of Subjects With Multiple Myeloma 2. **NCT00821600 - RIS-SCH-1012**: Single-Dose, Open-Label Pilot Study to Explore the Pharmacokinetics, Safety and Tolerability of a Gluteal Intramuscular Injection of a 4-Week Long-Acting Injectable Formulation of Risperidone in Patients With Chronic Stable Schizophrenia 3. **NCT01559272 - R092670PSY1005:** A Single-Dose, Open-Label, Randomized, Parallel-Group Study to Assess the Pharmacokinetics, Safety, and Tolerability of a Paliperidone Palmitate 3-Month Formulation in Subjects With Schizophrenia 4. **NCT01876966 - TMC125VIR1001**: A Phase I, Partially Randomized, Open Label, Two-way, Two Period Cross-over Study to Investigate the Pharmacokinetic Interaction Between Etravirine or Darunavir/Rtv and Artemether/Lumefantrine at Steady-state in Healthy HIV-negative Subjects 5. **NCT02195869 - PCYC-1129-CA:** A Multicenter Open-Label Phase 1b/2 Study of Ibrutinib in Steroid Dependent or Refractory Chronic Graft Versus Host Disease 6. **NCT03359291 - AC-055-122:** A Single-center, Open-label, One-sequence, Two-treatment Study to Investigate the Effect of Macitentan at Steady State on the Pharmacokinetics of Rosuvastatin in Healthy Male Subjects.

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:	

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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:	
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	
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:	