The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-3864
Date:	24 July 2019
Product Name:	Rilpivirine/Epoetin alfa/Darunavir
Therapeutic Area:	IDV/Oncology
Product Class:	Antiviral Agent/Hematologic Agents
Condition(s) Studied:	HIV/Anemia
Protocol Number(s) and Title(s):	**Rilpivirine:** NCT00540449 (TMC278-TIDP6-C209) A Phase III, Randomized, Double-blind Trial of TMC278 25 mg q.d. Versus Efavirenz 600mg q.d. in Combination With a Fixed Background Regimen Consisting of Tenofovir Disoproxil Fumarate and Emtricitabine in Antiretroviral-naive HIV-1 Infected Subjects NCT00543725 (TMC278-TIDP6-C215) A Phase III, Randomized, Double-blind Trial of TMC278 25mg q.d. Versus Efavirenz 600mg q.d. in Combination With a Background Regimen Containing 2 Nucleoside/Nucleotide Reverse Transcriptase Inhibitors in Antiretroviral-naive HIV-1 Infected Subjects **Darunavir:** NCT00071097 (TMC114-C202) A Phase II Randomized, Controlled, Partially Blinded Trial to Investigate Dose Response of TMC114/RTV in 3-class-experienced HIV-1 Infected Patients, Followed by an Open-label Period on the Recommended Dose of TMC114/RTV NCT00650832 (TMC114-C213) A Phase II Randomized, Controlled, Partially Blinded Trial to Investigate Dose-response of TMC114/RTV in 3-class-experienced HIV-1 Infected Subjects, Followed by an Open-label Period on the Recommended Dose of TMC114/RTV NCT00258557 (TMC114-C211) Phase III Randomized, Controlled, Open-label Trial to Investigate the Antiviral Activity, Tolerability and Safety of TMC114/r in Treatment- Naive HIV-1 Infected Patients **Epoetin alfa:** NCT00270283 (I88-009) A Double-Blind, Placebo-Controlled Study With Open-Label Follow-up to Determine the Safety and Efficacy of Subcutaneous Doses of r-HuEPO in AIDS Patients With Anemia Induced by Their Disease and AZT Therapy

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:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	

The YODA Project
Research Proposal Due Diligence Assessment

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