The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024 – 0356
Date:	April 25, 2024
Product Name:	Stelara/Prezista/Invokana/Plivensia/Tremfya/Procrit/Remicade
Therapeutic Area:	Immunology/IDV/CVM/Oncology
Product Class:	Antiviral agent/Antipsoriatics/Sodium-glucose co-transporter 2/Diabetes/Antirheumatic agents – biologic responders/interleukin-23 antagonist/Colony-stimulating factors
Condition(s) Studied:	Psoriasis/HIV Infections/Immunodeficiency Virus/Diabetes Mellitus, Type 2/Rheumatoid Arthritis/Psoriasis/Anemia critical illness/ Ulcerative Colitis/Crohn's Disease
Protocol Number(s) and Title(s):	1. NCT00267969 - C0743T08 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo Controlled Trial Evaluating the Efficacy and Safety of Ustekinumab (CNTO 1275) in the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis 2. 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-naïve HIV-1 Infected Subjects. 3. 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 4. NCT00454584 - C0743T12 - A Phase 3, Multicenter, Randomized Study Comparing CNTO 1275 and Etanercept for the Treatment of Moderate to Severe Plaque Psoriasis 5. NCT02431247 - TMC114FD2HTX3001 - WK48 - A Phase 3, Randomized, Active-controlled, Double-blind Study to Evaluate Efficacy and Safety of Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) Once Daily Fixed Dose Combination Regimen Versus a Regimen Consisting of Darunavir/Cobicistat Fixed Dose Combination Co-administered With Emtricitabine/Tenofovir Disoproxil Fumarate Fixed Dose Combination in Antiretroviral Treatment-naive Human Immunodeficiency Virus Type 1 Infected Subjects 6. NCT02065791 - 28431754DNE3001 - A Randomized, Double-blind, Event-driven, Placebo controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy 7. NCT01032629 - 28431754DIA3008 - A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of JNJ-28431754 on Cardiovascular Outcomes in Adult Subjects With Type 2 Diabetes Mellitus

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	8. NCT01989754 - 28431754DIA4003 - A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus 9. NCT02019472 - CNTO136ARA3005 - A Multicenter, Randomized, Double-blind, Parallel Group Study of Sirukumab Monotherapy Compared With HUMIRA® Monotherapy Administered Subcutaneously, in Subjects With Active Rheumatoid Arthritis 10. NCT01604343 - CNTO136ARA3002 - A Multicenter, Randomized, Double-blind, Placebo controlled, Parallel Group Study of CNTO 136 (Sirukumab), a Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Rheumatoid Arthritis Despite DMARD Therapy 11. NCT02207231 - CNTO1959PSO3001 - Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis 12. NCT03090100 - CNTO1959PSO3009 - A Phase 3, Multicenter, Randomized, Double-blind Study Evaluating the Comparative Efficacy of CNTO 1959 (Guselkumab) and Secukinumab for the Treatment of Moderate to Severe Plaque-type Psoriasis 13. NCT02207244 - CNTO1959PSO3002 - A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Study Evaluating the Efficacy and Safety of Guselkumab for the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis With Randomized Withdrawal and Retreatment 14. NCT00091910 - CR004114 (EPO-ICU-002) - A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of Epoetin Alfa in Critically Ill Subjects 15. - EPO-2 /// PR98-15-014 - Efficacy in the rHuEPO (Epoetin Alfa) in the Critically Ill Patient: A Randomized, Double Blind, Placebo-Controlled trial 16. NCT00036439 - C0168T37 - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis 17. NCT00096655 - C0168T46 - A Randomized, Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis 18. NCT01369355 - CNTO1275CRD3003 - A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects With Moderately to Severely Active Crohn's Disease

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:	