The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2023-5534
Date:	February 26, 2024
Product Name:	Spravato/Risperidal/Imbruvica/Erleada/Uptravi/Tremfya/Levaquin/Opsumit/ Darunavir/Plivensia/Stelara/Simponi/Vermox/Topamax
Therapeutic Area:	Neuroscience/Oncology/PH/Immunology/IDV
Product Class:	NMDA receptor antagonists/atypical antipsychotics/kinase inhibitors/androgen receptor inhibitors/selective nonprostanoid IP prostacyclin receptor antagonists/monoclonal antibodies/quinolone antiobiotics/endothelin receptor antagonists/monoclonal antibodies/biologics/second-generation anti-epiletic drugs/ sodium-glucose co-transporter 2 (SGLT2) inhibitors
Condition(s) Studied:	Depressive Disorder/ Chronic Lymphocytic Leukemia/Prostate Cancer/Pulmonary Arterial Hypertension/Psoriasis/Pneumonia/ Digital Ulcers/HIV Type 1/Rabies/Rheumatoid Arthritis/ Axial Spondyloarthritis/Helminth Infections/Asthma/IBD/Hypertension/ Ischemic Stroke/Diabetes Mellitus Type 2
Protocol Number(s) and Title(s):	1. **NCT02493868 - ESKETINTRD3003:** A Randomized, Double-blind, Multicenter, Active-Controlled Study of Intranasal Esketamine Plus an Oral Antidepressant for Relapse Prevention in Treatment-resistant Depression 2. **NCT00095134 - RIS-DEP-401:** A Double-Blind Study Comparing Adjunctive Risperidone Versus Placebo in Major Depressive Disorder That Is Not Responding to Standard Therapy 3. **NCT02133001 - ESKETINSUI2001**: A Double-blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Who Are Assessed to be at Imminent Risk for Suicide 4. **NCT02264574 - PCYC-1130-CA:** A Randomized, Multi-center, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor Ibrutinib in Combination With Obinutuzumab Versus Chlorambucil in Combination With Obinutuzumab in Subjects With Treatment-naïve Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma 5. **NCT01578707 - PCYC-1112-CA**: A Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor Ibrutinib (PCI-32765) Versus Ofatumumab in Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma 6. **NCT02489318 - 56021927PCR3002:** A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Apalutamide Plus Androgen Deprivation Therapy (ADT) Versus ADT in Subjects With Metastatic Hormone-sensitive Prostate Cancer (mHSPC)

	7. **NCT01946204 - ARN-509-003:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer 8. **NCT01106014 - AC-065A302:** A Multicenter, Double-blind, Placebo-controlled Phase 3 Study Assessing the Safety and Efficacy of Selexipag on Morbidity and Mortality in Patients With Pulmonary Arterial Hypertension 9. **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 **10. 91-113** 11. **NCT00034736 - CR002392/LOFBIV-PCAP-003:** A Multicenter, Randomized, Open-Label, Comparative Study to Compare the Efficacy and Safety of Levofloxacin and Standard of Care Therapy in the Treatment of Children With Community-Acquired Pneumonia in the Hospitalized or Outpatient Setting 12. **NCT01474122 - AC-055C302:** Prospective, Randomized, Placebo-controlled, Double-blind, Multicenter, Parallel Group Study to Assess the Efficacy, Safety and Tolerability of Macitentan in Patients With Ischemic Digital Ulcers Associated With Systemic Sclerosis 13. **NCT02269917 - TMC114IFD3013:** A Phase 3, Randomized, Active-controlled, Open-label Study to Evaluate the Efficacy, Safety and Tolerability of Switching to a Darunavir/ Cobicistat/ Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) Once-daily Single-tablet Regimen Versus Continuing the Current Regimen Consisting of a Boosted Protease Inhibitor (bPI) Combined With Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) in Virologically-suppressed, Human Immunodeficiency Virus Type 1 (HIV-1) Infected Subject 14. **NCT02431247 - TMC114FD2HTX3001:** 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 Coadministered With Emtricitabine/Tenofovir Disoproxil Fumarate Fixed Dose Combination in Antiretroviral Treatment-naive Human Immunodeficiency Virus Type 1 Infected Subject 15. **NCT02269917 - TMC114IFD3013:** A Phase 3, Randomized, Active-controlled, Open-label Study to Evaluate the Efficacy, Safety and Tolerability of Switching to a Darunavir/ Cobicistat/ Emtricitabine/ Tenofovir Alafenamide (D/C/F/TAF) Once-daily Single-tablet Regimen Versus Continuing the Current Regimen Consisting of a Boosted Protease Inhibitor (bPI) Combined With Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) in Virologically-suppressed, Human Immunodeficiency Virus Type 1 (HIV-1) Infected Subject

	16. **NCT02431247 - TMC114FD2HTX3001:** 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 Coadministered With Emtricitabine/Tenofovir Disoproxil Fumarate Fixed Dose Combination in Antiretroviral Treatment-naive Human Immunodeficiency Virus Type 1 Infected Subjects 17. **NCT01228383 - RAB-M-A008:** A Randomized, Single-blind, Active-controlled, Mono-center Phase II Study to Compare the Safety and Neutralizing Activity of Simulated Rabies Post-exposure Prophylaxis With CL184 in Combination With Purified Vero Cell Rabies Vaccine vs. Human Rabies Immune Globulin or Placebo in Combination With Purified Vero Cell Rabies Vaccine vs. CL184 or Placebo in Combination With Human Diploid Cell Rabies Vaccine in Healthy Adult Subjects 18. **NCT00656097 - RAB-M-A003:** A Randomized, Single-blind, Controlled, Monocentric Phase II Trial to Compare the Safety and Neutralizing Activity of Simulated Rabies Post-exposure Prophylaxis With CL184 in Combination With Rabies Vaccine vs. HRIG or Placebo in Combination With Rabies Vaccine in Healthy Adult Subjects 19. **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 20. **NCT02438787 - CNTO1275AKS3002:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Anti-TNF(Alpha) Refractory Subjects With Active Radiographic Axial Spondyloarthritis 21. **NCT02437162 - CNTO1275AKS3001:** A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Anti-TNF Alpha Naïve Subjects With Active Radiographic Axial Spondyloarthritis 22. **NCT01004432 - CNTO148ART3002:** Golimumab in Rheumatoid Arthritis Participants With an Inadequate Response to Etanercept (ENBREL) or Adalimumab (HUMIRA) 23. **NCT02034162 - MEBENDAZOLGAI3003:** A Double-Blind, Randomized, Multi-Center, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of a Single Dose of a 500-mg Chewable Tablet of Mebendazole in the Treatment of Soil-Transmitted Helminth Infections (Ascaris Lumbricoides and Trichuris Trichiura) in Pediatric Subjects 24. **NCT01173562 - MEBENDAZOLGAI3002:** An Open-Label, Single-Dose Study to Assess the Safety of 500-mg Mebendazole Chewable Formulation in Children 2 to 10 Years of Age, Inclusive

	25. **NCT00207740 - C0524T03:** A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-ranging Study Evaluating the Efficacy and Safety of CNTO 148 Administered Subcutaneously in Symptomatic Subjects With Severe Persistent Asthma 26. **NCT02407236 - CNTO1275UCO3001:** A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis 27. **NCT00488631 - C0524T18:** A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in Subjects With Moderately to Severely Active Ulcerative Colitis 28. **NCT00487539 - C0524T17:** A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis 29. **NCT00236665 - TOPMAT-OBHT-001:** A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese Patients With Mild to Moderate Essential Hypertension 30. **NCT00816166 - VISSIT CA-2007-01:** Phase III Study of Pharos Vitesse Neurovascular Stent System Compared to Best Medical Therapy for the Treatment of Ischemic Disease 31. **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 32. **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

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:	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes

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Comments:	*Anonymized data is shared with external research teams. During the anonymization process, the clinical data is transformed to ensure that the risk of re-identification is below the required threshold. This results in a loss of data utility which will impact the research described in the proposed project. For example, the amount of geographical information is limited. Country may be available, but the site location is always suppressed. In addition, demographic characteristics are generally considered indirect identifiers and may be suppressed or generalized, making it difficult to identify duplicate patients. Please refer to the dataset specification available for NCT01032629 on the YODA portal for more details on the Johnson & Johnson anonymization approach.*

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:	