

The YODA Project

Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2024-0668
Date:	11-July-2024
Product Name:	SIMPONI (Golimumab) REMICADE (Infliximab) STELARA (Ustekinumab)
Therapeutic Area:	Immunology
Product Class:	Antirheumatic agents - biologic response modifiers
Condition(s) Studied:	Ulcerative Colitis, Crohn's Disease
Protocol Number(s) and Title(s):	<p>1. 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</p> <p>2. 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</p> <p>3. NCT00488774 - C0524T16 A Phase 2/3 Multicenter, Randomized Placebo-controlled Double-blind Study to Evaluate the Safety and Efficacy of Golimumab Induction Therapy, Administered Intravenously, in Subjects With Moderately to severely Active Ulcerative Colitis</p> <p>4. NCT01863771 - CNT0148UCO3001 A Safety and Effectiveness Study of Golimumab in Japanese Patients With Moderately to severely Active Ulcerative Colitis</p> <p>5. NCT01988961 - CNT0148UCO2001 A Study to Evaluate the Accuracy of a Subset of the Length-109 Probe Set Panel (a Genetic Test) in Predicting Response to Golimumab in Participants With Moderately to severely Active Ulcerative Colitis</p> <p>6. NCT00036439 - C0168T37 A Randomized Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis</p> <p>7. NCT00096655 - C0168T46</p>

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	<p>A Randomized Placebo-controlled, Double-blind Trial to Evaluate the Safety and Efficacy of Infliximab in Patients With Active Ulcerative Colitis</p> <p>8. NCT00207675 - C0168T47 A Randomized Multicenter Open-label Study to Evaluate the Safety and Efficacy of Anti-TNF a Chimeric Monoclonal Antibody (Infliximab REMICADE) in Pediatric Subjects With Moderate to Severe CROHN'S Disease</p> <p>9. NCT00094458 - C0168T67 Multicenter, Randomized, Double-Blind, Active Controlled Trial Comparing REMICADE® (infliximab) and REMICADE plus Azathioprine to Azathioprine in the Treatment of Patients with Crohn's Disease Naive to both Immunomodulators and Biologic Therapy (Study of Biologic and Immunomodulator Naive Patients in Crohn's Disease)</p> <p>10. NCT00336492 - C0168T72 A Phase 3, Randomized, Open-label, Parallel-group, Multicenter Trial to Evaluate the Safety and Efficacy of Infliximab (REMICADE) in Pediatric Subjects With Moderately to Severely Active Ulcerative Colitis</p> <p>11. NCT00207662 - C0168T21 ACCENT I - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNFa Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long-term Treatment of Patients With Moderately to Severely Active Crohn's Disease</p> <p>12. NCT00207766 - C0168T26 ACCENT II - A Randomized, Double-blind, Placebo-controlled Trial of Anti-TNF Chimeric Monoclonal Antibody (Infliximab, Remicade) in the Long Term Treatment of Patients With Fistulizing CROHN'S Disease</p> <p>13. NCT00004941 - C0168T20 A Placebo-controlled, Repeated-dose Study of Anti-TNF Chimeric Monoclonal Antibody (cA2) in the Treatment of Patients with Enterocutaneous Fistulae as a Complication of Crohn's Disease</p> <p>14. NCT01551290 - CR018769; REMICADEUCO3001 A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Infliximab in Chinese Subjects With Active Ulcerative Colitis</p> <p>15. NCT00771667 - C0743T26 A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of</p>
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	<p>Ustekinumab Therapy in Subjects With Moderately to Severely Active Crohn's Disease Previously Treated With TNF Antagonist Therapy</p> <p>16. NCT01369329 - CNTO1275CRD3001 A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease Who Have Failed or Are Intolerant to TNF Antagonist Therapy (UNITI-1)</p> <p>17. NCT01369342 - CNTO1275CRD3002 A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects With Moderately to Severely Active Crohn's Disease (UNITI-2)</p> <p>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</p> <p>19. NCT00265122 - C0379T07 A Multicenter, Randomized, Phase 2a Study of Human Monoclonal Antibody to IL-12p40 (CNTO 1275) in Subjects With Moderately to Severely Active Crohn's Disease</p> <p>20. 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</p> <p>21. NCT01190839 - REMICADECRD3001 Prospective, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial Comparing REMICADE (Infliximab) and Placebo in the Prevention of Recurrence in Crohn's Disease Patients Undergoing Surgical Resection Who Are at Increased Risk of Recurrence</p>
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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:	

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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.	Yes
Comments:	