

| General Information | |
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| YODA Project (Protocol) ID: | 2025-0316 |
| Date Proposal Received by YODA Project: | 6-MAY-2025 |
| Product Name(s): | Canagliflozin (INVOKANA®) |
| Condition(s) Studied: | Diabetes Mellitus, Type 2 Obesity |
| NCT Number(s), Protocol Number(s) and Title(s): | <p>1. NCT02139943 - 28431754DIA2004 A Randomized Phase 2, Double-blind, Placebo-controlled, Treat-to-Target, Parallel-group, 3-arm, Multicenter Study to Assess the Efficacy and Safety of Canagliflozin as Add-on Therapy to Insulin in the Treatment of Subjects With Type 1 Diabetes Mellitus</p> <p>2. NCT01106651 - 28431754DIA3010 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin Compared With Placebo in the Treatment of Older Subjects With Type 2 Diabetes Mellitus Inadequately Controlled on Glucose Lowering Therapy</p> <p>3. NCT00642278 - 28431754DIA2001 A Randomized, Double-Blind, Placebo-Controlled, Double-Dummy, Parallel Group, Multicenter, Dose-Ranging Study in Subjects With Type 2 Diabetes Mellitus to Evaluate the Efficacy, Safety, and Tolerability of Orally Administered SGLT2 Inhibitor JNJ-28431754 With Sitagliptin as a Reference Arm</p> <p>4. NCT00968812 - 28431754DIA3009 A Randomized, Double-Blind, 3-Arm Parallel-Group, 2-Year (104-Week), Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-28431754 Compared With Glimepiride in the Treatment of Subjects With Type 2 Diabetes Mellitus Not Optimally Controlled on Metformin Monotherapy</p> <p>5. NCT01064414 - 28431754DIA3004 A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, 26-Week, Multicenter Study With a 26-Week Extension, to Evaluate the Efficacy, Safety and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus Who Have Moderate Renal Impairment</p> <p>6. NCT01081834 - 28431754DIA3005 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin as Monotherapy in the Treatment of Subjects With Type 2 Diabetes Mellitus Inadequately Controlled With Diet and Exercise</p> <p>7. NCT01106625 - 28431754DIA3002 A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With</p> |

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| | <p>Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Pioglitazone Therapy</p> <p>8. NCT01106677 - 28431754DIA3006 A Randomized, Double-Blind, Placebo and Active-Controlled, 4-Arm, Parallel Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Monotherapy</p> <p>9. NCT01106690 - 28431754DIA3012 A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sulphonylurea Therapy</p> <p>10. NCT01137812 - 28431754DIA3015 A Randomized, Double-Blind, Active-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin Versus Sitagliptin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sulphonylurea Therapy</p> <p>11. NCT01340664 - 28431754DIA2003 A Randomized, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin</p> <p>12. NCT01381900 - 28431754DIA3014 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, 18-Week Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin Alone or in Combination With a Sulphonylurea</p> <p>13. NCT01809327 - 28431754DIA3011 A Randomized, Double-Blind, 5-Arm, Parallel-Group, 26-Week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in Combination With Metformin as Initial Combination Therapy in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control With Diet and Exercise</p> <p>14. NCT02025907 - 28431754DIA4004 A Randomized, Double-blind, Placebo Controlled, 2-arm, Parallel-group, 26-week, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Canagliflozin in the Treatment of Subjects With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Metformin and Sitagliptin Therapy</p> <p>15. NCT01032629 - 28431754DIA3008</p> |
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Data Sharing Request Due Diligence Assessment

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| | <p>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 16. NCT01989754 - 28431754DIA4003</p> <p>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 17. NCT00650806 - 28431754OBE2001</p> <p>A Randomized, Double-Blind, Placebo-Controlled Nondiabetic Overweight and Obese Subjects 18. NCT02243202 - 28431754OBE2002</p> <p>A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Investigate the Safety and Efficacy of the Co-administration of Canagliflozin 300 mg and Phentermine 15 mg Compared With Placebo for the Treatment of Non-diabetic Overweight and Obese Subjects 19. NCT02065791 - 28431754DNE3001</p> <p>A Randomized, Double-blind, Event-driven, Placebocontrolled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy</p> |
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Proposal Review

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| <p>Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. Is there any reason why the study/studies listed should no longer be shared?</p> | No |
| Comments if 'Yes': | |
| <p>Question 2: On review of the proposal, is there any data that has been requested that may be missing from the clinical database?</p> | No |
| Comments if 'Yes': | |
| <p>Question 3: Is a similar analysis underway, or completed and pending disclosure by J&J?</p> | Yes |
| Comments if 'Yes': | |