

RESEARCH AS PRINCIPAL INVESTIGATOR

"An 8 week randomized , double-blind, parallel group, multi-center , placebo and active controlled dose escalation study to evaluate the efficacy and safety of aliskarin (150mg and 300mg) administered alone and in combination with valsartan (160mg and 320mg) in patients with hypertension" , Phase III, Novartis Pharmaceuticals

"A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Sequential-Design Study to Evaluate the Lipid-Altering Efficacy and Tolerability of MK-0354 in Patients With Dyslipidemia", Phase IIa, Merck & Co., Inc.

"Impact of a Self-Adjusted Titration Guideline in Subjects with Type 2 Diabetes Mellitus: A 6-Month, Multicenter, Open-Label, Randomized, Parallel-Group, Treat-to-Target of the Efficacy and Safety of Detamir" Phase IV, Novo Nordisk Pharmaceuticals.

"Glycemic Optimization Trial (GOT): To Assess The Safety Of Glucose Control As Measured By The Frequency Of Severe Hypoglycemia Events Using Dosing Algorithms Based On Different Fasting Blood Glucose Goals with Lantus (Insulin Glargine [rDNA Origin]) In Adult Individuals With Type 2 Diabetes Who Have Not Achieved The Target A_{1c} of <7% With Oral Hypoglycemia Agents: A Randomized, Open-Label, Parallel- Design Trial", Phase IV, Aventis Pharmaceuticals

TREAT "Trial to Reduce Cardiovascular Events with Aranesp Therapy" , Phase III, Amgen Inc.

"A Phase 2b, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Ranging Study of YM 443 in Subjects with Functional Dyspepsia, Phase IIb, Yamanouchi Pharma America, Inc.

"A multi-center, randomized, double-blind, placebo controlled study of the effect of SSRI 80575 at two doses for 24 weeks treatment on the rate of regeneration of epidermal nerve fibers in patients with mild diabetic peripheral neuropathy." Phase II, Sanofi- Aventis.

"An Open-Label, Single-arm Study to Assess the Safety of Aranesp Manufactured by a Serum Free Bioreactor Technology in Subjects with Chronic Kidney Disease", Phase III Amgen Inc.

"A randomized, double blind, placebo controlled, parallel group study to assess the effect of the endothelin receptor antagonist Avosentan on time to doubling of serum creatinine, end stage renal disease or death in patients with type 2 diabetes mellitus and diabetic nephropathy." Phase III, Speedel Pharma Ltd.

"A randomized, double blind, placebo-controlled, parallel-group, multicentered study to assess the efficacy and safety of long-term administration of Rimonabant in the prevention of type 2 diabetes in patients with prediabetic status." Phase III, Sanofi-

Aventis.

"A randomized, double-blind, active-controlled, multicenter study to compare the effect of 24 weeks treatment with fixed combination therapy of Vildagliptin and metformin to the individual monotherapy components in drug naïve patients with type 2 diabetes" Phase III, Novartis Pharmaceuticals.

"All To Target Trial Lantus® (insulin glargine) with stepwise addition of APIDRA® (insulin glulisine or Lantus with one injection of Apidra vs. a twice-daily premixed insulin regimen (Novolog® Mix 70/30™) in adult subjects with type 2 diabetes failing dual or triple therapy with oral agents: a 64-week, multi-center, randomized, parallel, open-label clinical study," Phase IV, Sanofi-Aventis.

"An 8 week Prospective, Multicenter, Randomized, Double-Blind, Active Control, Parallel Group Study to Evaluate the Efficacy and Safety of Aliksiren HCTZ versus Amlodipine in African American Patients with Stage 2 Hypertension" Phase IV, Novartis Pharmaceuticals.

"An 8-week Randomized, Double-Blind, Active Control, Dose Escalation Study to Evaluate the Efficacy and Safety of Aliskinin HCTZ (300/25 mg) Compared to HCTZ (25 mg) in Older Patients with Stage 2 Systolic Hypertension" Phase IV, Novartis Pharmaceuticals.

"A Double Blind, Active-Controlled, Long term, Safety Extension Study of Optimized Doses of Darusentan in Subjects with Resistant Hypertension Despite Receiving Three or more Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine" Phase IV, Gilead Sciences, Inc.

"A Double-Blind, Placebo- and Active-Controlled, Multi-Center, Parallel Group Study to Evaluate the Safety and Efficacy of Darusentan in Subjects with Resistant Hypertension Receiving Combination Therapy with Three or more Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine" Phase III, Gilead Sciences, Inc.

"A Multi-center Randomized, Double-Blind, Parallel Design Trial to Evaluate the Blood Pressure Lowering Efficacy Comparing Moderate versus Aggressive Treatment Regimen on Exforge in Patients Uncontrolled on ARB Monotherapy" Phase III, Novartis Pharmaceuticals.

"An 8 Week Randomized, Double-Blind, Parallel-Group, Multicenter, Active-Controlled Dose Escalation Study to Evaluate the Efficacy and Safety of Aliskiren HCTZ (300/125mg) Compared to Amlodipine (10 mg) in Patients with Stage 2 Systolic Hypertension and Diabetes Mellitus" Phase IV, Novartis Pharmaceuticals.

"A Multi-center, Randomized, Double - blind Study to Evaluate the Efficacy and Long-term Safety of Vildagliptin Modified Release (MR) as Monotherapy in Patients with Type 2 Diabetes" Phase II/III, Novartis Pharmaceuticals.

"A Randomized, Observer-blind, Active-controlled Study to Demonstrate the Superior Efficacy of GSK Biologicals Adjuvanted Influenza Vaccine GSK2186877A Administered Intramuscularly in Elderly Aged 65 or Above as Compared to Fluarix TM" Phase III, Glaxo, Smith, Kline Pharmaceuticals.

"A 12-week multicenter, randomized, double-blind, parallel group, active-control study to evaluate the antihypertensive efficacy and safety of an Exforge® (valsartan/amlodipine)-based regimen versus a losartan based regimen in patients with Stage 2 systolic hypertension," Phase III, Novartis Pharmaceuticals.

"A multicenter, randomized, double blind, parallel design trial to evaluate the blood pressure lowering efficacy comparing moderate versus aggressive treatment regimen of Exforge in patients uncontrolled on ARB monotherapy," Phase II/III, Novartis Pharmaceuticals.

"An 8 week Randomized, Double-Blind, Parallel Group, Multi-Center, Active Controlled Study to Evaluate the Efficacy and Safety of Valsartan Administered in Combination with Aliskiren (160/150 mg, 320/300 mg) versus Valsartan alone (160 mg, 320 mg) in Patients with Stage 2 Hypertension," Phase III, Novartis Pharmaceuticals.

"An 8-week Multicenter, Randomized, Double-blind, Active Control, Parallel Group Study to Evaluate the Efficacy and Safety of Aliskiren Administered in Combination with Amlodipine (150/5 mg, 300/10 mg) versus Amlodipine alone (5 mg, 10 mg) in African American Patients with Stage 2 Hypertension," Phase III, Novartis Pharmaceuticals.

"A 12-week multi-center, randomized, double-blind, placebo controlled, parallel-group adaptive design study to evaluate the efficacy on blood glucose control and safety of five doses of LCQ908 (2, 5, 10, 15 and 20 mg) or sitagliptin 100 mg on a background therapy of metformin in obese patients with type 2 diabetes," Phase II, Novartis Pharmaceuticals.

"A multi-center, randomized, double-blind, active-controlled clinical trial to evaluate the safety and tolerability of 24 weeks treatment with vildagliptin (50 mg qd or 100 mg qd) versus sitagliptin (25 mg qd) in patients with type 2 diabetes and severe renal insufficiency," Phase IIIb, Novartis Pharmaceuticals.

"A 28 week extension to a 24 week multi-center, randomized, double-blind, active-controlled clinical trial to evaluate the safety and tolerability of vildagliptin 50 mg qd versus sitagliptin 25 mg qd in patients with type 2 diabetes and severe renal insufficiency," Phase IIIb, Novartis Pharmaceuticals.

"A Multicenter, Randomized, Double-Blind, Assessor-Blind, Non-Inferiority Study Comparing the Efficacy and Safety of Once-Weekly subcutaneous Inrabiotaparinux (SSR126517E) with Oral Adjusted-Dose Warfarin in the Prevention of Stroke and Systemic Thromboembolic Events in Patients with Atrial Fibrillation", Phase III, Sanofi-Aventis.

"A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction," Phase III, Novartis Pharmaceuticals.

"A 36-week, randomized, double-blind, multi-center, parallel group, active controlled study to evaluate the efficacy, safety and tolerability of LCZ696 compared to valsartan in patients with chronic heart failure and preserved left-ventricularejection fraction, "Phase III, Novartis Pharmaceuticals.

" A randomized, placebo-controlled 2-arm parallel-group, multicenter study with a 24-week double-blind treatment period assessing the efficacy and safety of lixisenatide in patients with Type 2 diabetes insufficiently controlled with insulin glargine and metformin," Phase II, Sanofi-Aventis.

"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate Cardiovascular Outcomes during Treatment with Lixisenatide in Type 2 Diabetic Patients after an Acute Coronary Syndrome," Phase III, Sanofi-Aventis.

"A Long-term, Multi-centre, International, Randomised, Double-Blind, Placebo-controlled Trial to Determine Liraglutide Effects on Cardiovascular Events," Phase III, Novo Nordisk.

"A Phase IIIb, 24-week, randomized, placebo-controlled, double-blinded, efficacy and safety study of linagliptin in Black/African American patients with type 2 diabetes with a MTT sub-study," Phase III b, Boehringer Ingelheim.

"An open label randomized multicenter study to assess patient preference for and evaluate clinical benefit of insulin glargine (Lantus®) SoloSTAR® pen versus conventional vial/syringe method of insulin glargine (Lantus®) injection therapy in patients with type 2 diabetes mellitus," Phase IV, Sanofi-Aventis.

" A mulitcentre, international, randomized, parallel group, double blind study to evaluate Cardiovascular safety of linagliptin versus glimepride in patients with type 2 diabetes mellitus at high cardiovascular risk. The CAROLINA Trial," Phase III. Sanofi-Aventis.

" A phase III randomized, double-blind, parallel group study to evaluate the efficacy and safety of once daily oral administration of BI10773 25 mg/linagliptin 5 mg and BI 10773 10 mg/linagliptin 5 mg Fixed Dose Combination tablets compared with the individual components (BI 10773 25 mg, BI 10773 IO mg, and linagliptin 5 mg) for 52 weeks in treatment nai"ve and metformin treated patients with type 2 diabetes mellitus with insufficient glycaemic control." Phase III, Boehringer Ingelheim,

"Protocol H9X-MC-GBDJ (REWIND). The Effect of LY21 89265 on Major Cardiovascular Events in Patients with Type 2 Diabetes: Reducing Cardiovascular Events with a Weekly INcretin in Diabetes (REWIND)". Phase III, Eli Lilly and Co.

"A randomized, 24-week, open-label, 2-arm parallel-group, multicenter study comparing the efficacy and safety of insulin glargine/lixisenatide fixed ration combination versus insulin glargine on top of metformin in type 2 diabetic patients." Phase III, Sanofi-Aventis.

"Protocol F3Z-MC-IOQH(a). A Randomized, Double-Blind, Crossover Trial Comparing the Safety and Efficacy of Insulin Lispro with the Safety and Efficacy of Insulin Aspart in Subjects with Type 2 Diabetes on CSII Therapy." Phase IIIb, Eli Lilly and Co.
"EFC1 1628, 6-month, Multicenter, Randomized, Open-label, Parallel group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® both plus Mealtime Insulin in Patients with Type 2 Diabetes Mellitus with a 6-month Safety Extension Period." Phase III, Sanofi-Aventis.

"EFC1 1629, 6-month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® both in combination with oral antihyperglycemic drug(s) in Patients with Type 2 Diabetes Mellitus with a 6-month Safety Extension Period." Phase III, Sanofi-Aventis.

"ACT12374, A Randomized, 24-Week, Open-Label, 2-arm Parallel-Group, Multicenter Study Comparing the Efficacy and Safety of Insulin Glargine/Lixisenatide Fixed-Ratio Combination Versus Insulin Glargine on top of Metformin in Type 2 Diabetic Patients." Phase III, Sanofi.

CEP237/Z25/G "ASPIRE (Automation to Simulate Pancreatic Insulin Response): Pivotal In Home Study to determine Safety and Efficacy of the LGS Feature in Sensor-Augmented Pumps." Medtronic Diabetes

"Protocol 12R-MC-BIAM. The impact of LY2605541 versus Insulin Glargine for Patients with Type 2 Diabetes Mellitus Advanced to Multiple Injection Bolus with Insulin Lispro: a Double-Blind Randomized, 26-Week Study. The IMAGINE 4 Study" Phase III, Eli Lilly and Co.

"Protocol MB102077. A multicenter, Randomized, Double-Blind, Placebo controlled, Parallel Group, Phase 3 Trial to Evaluate the safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes and inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) and an additional Antihypertensive medication.", Phase III, BMS.

"Protocol MB102073. A multicenter, Randomized, Double-Blind, Placebo controlled, Parallel Group, Phase 3 Trial to Evaluate the safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes and inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB).", Phase III, BMS.

"Protocol B1261007-A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Evaluate the Efficacy and Safety of Once-daily Administration of a Chemokine CCR2/5 Receptor Antagonist (Pf 04634817) in Adults with Type 2 Diabetes and Overt Nephropathy." Pfizer.

"BMS CV:181169: A Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Add-On Therapy with Saxagliptin and Dapagliflozin added to Metformin compared to Add-On Therapy with Saxagliptin in combination with Metformin or Dapagliflozin in combination with Metformin in Subjects with Type 2 Diabetes who have inadequate Glycemic Control on Metformin Alone." Bristol-Meyers Squibb.

" AVE0010-EFC12626 GETGOAL DUO-2 A Randomized, Open-label, Active-controlled, 3-arm Parallel-group, 26-week study comparing the Efficacy and Safety of Lixisenatide to that of Insulin Glulisine Once Daily and Insulin Glulisine Three Times Daily in Patients with Type 2 Diabetes Insufficiently Controlled with Insulin Glargine with or without Metformin." Sanofi.

"EFC12347 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Non-Insulin Antihyperglycemic Drugs with a 6-month Safety Period." Sanofi.

" EFC12456 A 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® Injected in the Morning or Evening in Patients with Type 1 Diabetes Mellitus with a 6-month Safety Extension Period." Sanofi.

" Protocol IBHC-Two Treatment Approaches for Humulin Regular U-500 Insulin (Thrice-Daily versus Twice-Daily) in Subjects with Type 2 Diabetes Mellitus Not Achieving Adequate Glycemic Control on High-Dose U-100 Insulin Therapy with or without Oral Agent: A Randomized, Open-Label, Parallel Clinical Trial. Eli Lilly and Co.

"CV181169 A Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Add-On therapy with Saxagliptin and Dapagliflozin added to Metformin compared to Add-On Therapy with Saxagliptin in combination with Metformin or Dapagliflozin in combination with Metformin in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin Alone." Bristol-Myers Squibb.

"CEP266/Z25/B-EDMS A post Approval Study of the TS (Threshold Suspend) Feature with a Sensor-Augmented Pump System. " Medtronic Diabetes

"EX1250-4080 A trial comparing cardiovascular safety of insulin degludec versus insulin glargine in subjects with type 2 diabetes at high risk of cardiovascular events" Novo Nordisk

"NN921 1-3919 The efficacy and safety of liraglutide as adjunct therapy to insulin in the treatment of type 1 diabetes." Novo Nordisk

"NN921 1-4083 The efficacy and safety of liraglutide adjunct to insulin treatment in type 1 diabetes: A 26-weeks randomised insulin capped, placebo-controlled, double-blind, parallel group, multinational, multi-centre trial." Novo Nordisk

"28431 754DIA4004 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." Janssen

"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" Janssen

"EFC12405 A randomized, 30-week, active-controlled, open label, 2-treatment arm, parallel-group, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine with or without metformin in patients with T2DM." Sanofi

"EFC12404 A randomized, 30-week, active-controlled, open label, 3-treatment arm, parallel-group, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine alone and to lixisenatide alone on top of metformin in patients with Type 2 diabetes mellitus." Sanofi

"EFC13403 Six month, randomized, open-label comparison of the insulin analog SAR342432 to Humalog in adult patients with type 2 diabetes mellitus also using insulin glargine" Sanofi

" PDY13502 A Randomized, 2X4 Week, Active-Controlled, Open-Label, 2-Treatment Arm, 2-Period Cross-Over Study assessing the safety of SAR342434 and Humalog used in continuous subcutaneous insulin infusion (CSII) in adult patients with type I diabetes mellitus (T1 DM)" Sanofi

"MBI 02229 A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 study to evaluate the efficacy and safety of Dapagliflozin as an Add-on to insulin therapy in subjects with Type I Diabetes Mellitus" AstraZeneca AB (Study being conducted by Bristol-Myers Squibb on behalf of AstraZeneca AB)

"LX4211. 1-1-309-T1DM A Phase 3, Randomized, Double-blind, Placebo controlled, Parallel-group, multicenter study to evaluate the efficacy, safety and tolerability of LX4211 as Adjunct Therapy in Adult Patients with Type 1 Diabetes Mellitus Who Have Inadequate Glycemic Control with Insulin Therapy" Lexicon Pharmaceuticals, Inc.

"LPS14354 A Randomized, Open-Label, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab versus Usual Care in Patients with Type 2 Diabetes and Mixed Dyslipidemia at High Cardiovascular Risk with Non-HDL-C Not Adequately Controlled with Maximally Tolerated Statin Therapy" Sanofi

"LPS 14587 A Randomized, Active-Controlled, Parallel Group, 16-Week Open Label Study Comparing the Efficacy and Safety of the Morning Injection of Toujeo (Insulin Glargine-U300) Versus Lantus in Patients with Type 1 Diabetes Mellitus" Sanofi

"NN9924-4221 PIONEER 6 - Cardiovascular outcomes. A trial investigating the cardiovascular safety of oral semaglutide in subjects with type 2 diabetes.

"EFC15081 Gemelli 1-Six-month, Randomized, Open-label, Parallel-group Comparison of SAR341402 to Novolog®/NovoRapid® in Adult Patients with Diabetes Mellitus Also Using Insulin Glargine, with a 6-month Safety Extension Period" Sanofi

"NN9535-4269 SUSTAIN9-Add-on to SGLT-2i; Efficacy and Safety of Semaglutide Once-weekly Versus Placebo as Add-on to SGLT-2i in Subject with Type 2 Diabetes Mellitus" Novo Nordisk

" EFC14837 SOTA-CKD3-A Randomized, Double-blind, Placebo Controlled, 3-arm, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Moderate Renal Impairment who have Inadequate Glycemic Control" Sanofi

"EFC15166 SOTA-CKD4- A Randomized, Double-blind, Placebo Controlled, 3-arm, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Severe Renal Impairment who have Inadequate Glycemic Control" Sanofi