

CTI - Diabetes February 2010

Adis Clinical Trials Insight: Ongoing Trials – Status Tracking February 2010

Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
1 700050605	Acarbose Vildagliptin	Recruiting	III	Vildagliptin + acarbose: pharmacodynamics Effect of vildagliptin on endothelium-dependent vasodilatation In patients with type 2 diabetes mellitus	
2 700048577	Acarbose Voglibose	Recruiting	IV	Acarbose vs Voglibose: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with insulin glargine alone or in combination with metformin based on glycaemic control	Bayer, Bayer HealthCare
3 700042570	ARRY-403	Completed	I	ARRY 403: adverse reactions Various toxicities In patients with type 2 diabetes mellitus	Array BioPharma
4 700046498	Atorvastatin	Completed	IV	Atorvastatin: pharmacodynamics Effects on pancreatic beta-cell function and insulin resistance In patients with type 2 diabetes mellitus	
5 700027145	Atorvastatin	Active, no longer recruiting	II	Atorvastatin: therapeutic use Type 1 diabetes mellitus In children and adolescents with newly diagnosed disease	
6 700019161	Chromium	Completed	IV	Chromium: therapeutic use Type 2 diabetes mellitus	
7 700047768	Colesevelam	Recruiting	IV	Colesevelam: pharmacodynamics Assessing effect on disposition index and incretin concentrations In patients with type 2 diabetes mellitus	Daiichi Sankyo Inc
8 700037016	Dapagliflozin	Completed	III	Dapagliflozin: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled on diet and exercise alone	AstraZeneca, Bristol-Myers Squibb
9 700051820	Dexamethasone	Recruiting	II	Dexamethasone: therapeutic use Diabetic macular oedema Intravitreal injection in diabetic patients undergoing cataract surgery	
10 700016921	Dexamethasone	Active, no longer recruiting	I/II	Dexamethasone: therapeutic use Diabetic macular oedema Phase I/II trial of intravitreal implant	Sanwa Kagaku Kenkyusho
11 700048010	Dutogliptin Sitagliptin	Discontinued	III	Dutogliptin vs sitagliptin: adverse reactions Various toxicities	Forest Laboratories, Phenomix

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In type 2 diabetes mellitus patients with moderate and severe renal impairment including patients on haemodialysis Corporation

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12 700036607	Exenatide Sitagliptin	Completed	IV	Exenatide vs sitagliptin: therapeutic use Type 2 diabetes mellitus In patients with inadequate glycaemic control on metformin or a thiazolidinedione	Amylin Pharmaceuticals, Eli Lilly
13 700000200	Flutamide Metformin	Completed	II	Metformin + flutamide: pharmacodynamics Effects on ovarian and adrenal function In adolescent females with type 1 diabetes mellitus	
14 700035720	Glimepiride Insulin-glargine Metformin	Completed	IV	Glimepiride, insulin glargine, metformin: therapeutic use Type 2 diabetes mellitus Drugs in various combination	sanofi-aventis
15 700052498	Glucagon-like-peptide-1	Recruiting	I	Glucagon-like peptide-1: adverse reactions Various toxicities Phase I trial of drug therapy, delivered via CellBeads technology, to patients with type-2 diabetes mellitus	AstraZeneca, Biocompatibles International, CellMed
16 700048884	GSK-1614235 Sitagliptin	Active, no longer recruiting	I	GSK 1614235 vs sitagliptin: adverse reactions Various toxicities In patients with type 2 diabetes mellitus and effect of food in volunteers	GlaxoSmithKline
17 700022276	Insulin	Completed	IV	Insulin: therapeutic use Type 1 diabetes mellitus Comparison of Paradigm real time system to self-monitoring blood glucose	Medtronic
18 700030537	Insulin Insulin-glargine Insulin-glulisine	Completed	IV	Insulin glargine + insulin glulisine vs insulin: therapeutic use Type 2 diabetes mellitus In patients undergoing non-cardiac elective or emergency surgery	sanofi-aventis
19 700030453	Insulin-aspart Insulin-detemir	Completed	IV	Insulin aspart + insulin detemir: therapeutic use Type 2 diabetes mellitus Subcutaneous protocol coupled with rapid initiation of bolus vs usual care	Novo Nordisk
20 700039349	Insulin-aspart Insulin-detemir Insulin-suspension-isophane	Active, no longer recruiting	IV	Insulin aspart + insulin detemir, insulin suspension isophane: pharmacodynamics Effects on change in fat distribution In overweight and obese patients with type 2 diabetes mellitus	Novo Nordisk, Novo Nordisk Pharma

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21 700046517	Insulin-aspart Insulin-suspension-isophane	Recruiting	IV	Insulin aspart + insulin suspension isophane: therapeutic use Diabetes in pregnancy, glucose intolerance Effect of strict periconceptional glycaemic control on neonatal outcomes in patients conceiving assisted reproductive technology	LifeScan
22 700037058	Insulin-aspart/insulin-protamine-aspart	Completed	IV	Insulin aspart/insulin protamine aspart: therapeutic use Type 1 diabetes mellitus, type 2 diabetes mellitus	Novo Nordisk, Novo Nordisk Pharma
23 700041388	Insulin-aspart/insulin-protamine-aspart	Completed	III	Insulin-aspart/insulin protamine aspart: adverse reactions Hypoglycaemia In patients with type 2 diabetes mellitus	Novo Nordisk
24 700050920	Insulin-aspart/insulin-protamine-aspart Insulin-degludec/insulin-aspart	Active, no longer recruiting	III	Insulin degludec/insulin aspart vs insulin aspart/insulin protamine aspart: therapeutic use Type 2 diabetes mellitus In patients whose disease is inadequately controlled with insulin +/- oral antihyperglycaemics	Novo Nordisk
25 700046681	Insulin-aspart/insulin-protamine-aspart Insulin-glargine Insulin-glulisine	Recruiting	IV	Insulin glargine + insulin glulisine vs insulin aspart/insulin protamine aspart: therapeutic use Type 2 diabetes mellitus	sanofi-aventis
26 700052649	Insulin-degludec/insulin-aspart Insulin-glargine	Recruiting	III	Insulin degludec/insulin aspart vs insulin glargine: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with insulin and oral antihyperglycaemics	Novo Nordisk
27 700052699	Insulin-degludec/insulin-aspart Insulin-glargine	Recruiting	III	Insulin degludec/insulin aspart vs insulin glargine: therapeutic use Type 2 diabetes mellitus In type 2 diabetes mellitus patients receiving metformin + at least one oral antihyperglycaemic	Novo Nordisk
28 700033785	Insulin-detemir	Completed	IV	Insulin detemir: adverse reactions Various toxicities Phase IV observational trial of Levemir FlexPen in patients with diabetes mellitus	Novo Nordisk
29 700039236	Insulin-detemir	Recruiting	IV	Insulin detemir: therapeutic use Type 2 diabetes mellitus	Novo Nordisk, Novo Nordisk Pharma

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30 700040799	Insulin-detemir	Completed	IV	Insulin detemir: therapeutic use Type 2 diabetes mellitus In patients who were previously treated with NPH as basal insulins	Novo Nordisk
31 700037395	Insulin-glargine Taspoglutide	Recruiting	III	Taspoglutide vs insulin glargine: therapeutic use Type 2 diabetes mellitus In patients with insulin-naive disease, inadequately controlled with metformin and sulphonylurea combination therapy	Ipsen, Roche
32 700053204	Insulins	Recruiting	IV	Insulins: therapeutic use Type 2 diabetes mellitus Quality-of-life trial in Japanese patients	Eli Lilly
33 700047511	JNJ-38431055	Discontinued	I	JNJ 38431055: adverse reactions Various toxicities In patients with type 2 diabetes mellitus	Johnson & Johnson Pharmaceutical Research & Development
34 700053053	JNJ-38431055 Sitagliptin	Recruiting	I	JNJ38431055, sitagliptin: pharmacodynamics Effect on glucagon like peptide 1 levels Drugs alone or in combination in overweight or obese patients	Johnson & Johnson Pharmaceutical Research & Development
35 700035936	Lixisenatide	Active, no longer recruiting	III	Lixisenatide: therapeutic use Type 2 diabetes mellitus In patients with insufficiently controlled with basal insulin with or without metformin	sanofi-aventis, Sanofi-Synthelabo
36 700043276	LY-2409021	Completed	II	LY 2409021: therapeutic use Type 2 diabetes mellitus In patients either controlling disease through diet and exercise alone, or with diet and exercise taking metformin	Eli Lilly
37 700039845	LY-2428757	Completed	II	LY 2428757: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with diet and exercise alone, or in combination with metformin	Eli Lilly
38 700040260	MBX-102 Pioglitazone	Discontinued	II	MBX 102 vs pioglitazone: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with a stable dose of metformin	Metabolex
39 700000016	Metformin	Completed	II	Metformin: pharmacodynamics Effects on endothelial function and adipocyte AMPK activation	

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				In patients with diabetes mellitus	
40 700029941	Metformin Omega-3-ethylester-concentrate	Active, no longer recruiting	III	Metformin +/- omega-3-ethylester concentrate: pharmacodynamics Effects of fatty acid delivery on myocardial metabolism and function In patients with type 2 diabetes mellitus	
41 700049409	NOX-E36	Completed	I	NOX E36: adverse reactions Various toxicities Phase I trial in healthy volunteers	NOXXON Pharma AG
42 700047412	Otelixizumab	Active, no longer recruiting	I	Otelixizumab: adverse reactions Various toxicities In patients with type 1 diabetes mellitus	GlaxoSmithKline
43 700000019	Pamidronic-acid	Completed	II	Pamidronic acid: therapeutic use Diabetic foot In patients with diabetes mellitus and Charcot's arthropathy	
44 700043393	Pegaptanib	Not yet recruiting	IV	Pegaptanib: therapeutic use Prevention of diabetic retinopathy	Pfizer
45 700052526	PF-4937319	Recruiting	I	PF 4937319: adverse reactions Various toxicities Tolerability, pharmacokinetics, and pharmacodynamics in adults with type 2 diabetes mellitus	Pfizer
46 700025702	Pioglitazone	Completed	IV	Pioglitazone: pharmacodynamics Effects on cardiac function and large arteries In patients with type 2 diabetes: The PICCOLA trial	Takeda Global Research and Development Center
47 700035897	Pioglitazone Sitagliptin	Active, no longer recruiting	III	Pioglitazone, sitagliptin: therapeutic use Type 2 diabetes mellitus Comparing drugs alone and in combination in patients who have inadequate glycemic control	Merck & Co, Merck Sharp & Dohme, Merck Sharp & Dohme Italia
48 700045477	Pioglitazone Taspoglutide	Recruiting	III	Taspoglutide vs pioglitazone: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with sulfonylurea monotherapy or sulfonylurea plus metformin combination therapy	Roche
49 700028905	Pregabalin	Completed	III	Pregabalin: adverse reactions Various toxicities Phase III open-label extension study in patients with painful diabetic peripheral neuropathy who have completed 13 weeks of dosing in study A0081163	Pfizer

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50 700039526	RO-4998452	Recruiting	II	RO 4998452: therapeutic use Type 2 diabetes mellitus	Roche
51 700006159	Rosiglitazone	Completed	I	Rosiglitazone: adverse reactions Various toxicities Phase I trial of the effects on cardiac mass and function in male patients with type 2 diabetes mellitus	
52 700000091	Rosiglitazone Sulfonylureas	Completed	II	Rosiglitazone, sulfonylureas: pharmacodynamics Effects on cardiac ischaemia, blood pressure and associated risk factors In patients with chronic stable angina and type 2 diabetes mellitus	GlaxoSmithKline
53 700043868	Sitagliptin	Recruiting	II	Sitagliptin: pharmacodynamics Effects on secretion of glucose, insulin, glucagon, C-peptide and lipid profile In patients with type 2 diabetes mellitus	
54 700051670	SRT-2379	Recruiting	I	SRT 2379: therapeutic use Various toxicities In volunteers under fasted and fed conditions	GlaxoSmithKline
55 700034572	Taspoglutide	Recruiting	III	Taspoglutide: therapeutic use Type 2 diabetes mellitus In patients with disease inadequately controlled with diet and exercise	Roche
56 700038158	Taspoglutide	Recruiting	III	Taspoglutide: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with metformin plus pioglitazone	Roche
57 700000034	Triamcinolone	Completed	III	Triamcinolone: therapeutic use Diabetic macular oedema In patients with laser treatment-refractory disease	
58 700049584	XOMA-052	Recruiting	II	XOMA 052: therapeutic use Type 2 diabetes mellitus Phase IIb, dose-ranging study	XOMA

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