

CTI - Diabetes January 2010



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

The table below highlights the ongoing trials whose status has changed during January 2010

Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
1 700030562	Exenatide	Completed	III	Exenatide: therapeutic use Type 2 diabetes mellitus Phase III trial in Japanese patients poorly controlled on oral diabetics	Amylin Pharmaceuticals, Eli Lilly
2 700040260	MBX-102 Pioglitazone	Active, no longer recruiting	II	MBX 102 vs pioglitazone: therapeutic use Type 2 diabetes mellitus In patients inadequately controlled with a stable dose of metformin	Metabolex
3 700040714	Vildagliptin	Active, no longer recruiting	II/III	Vildagliptin: therapeutic use Type 2 diabetes mellitus In treatment-naive patients	Novartis
4 700043961	APN-01	Completed	I	APN 01: adverse reactions Various toxicities In volunteers	Apeiron Biologics
5 700035152	Insulin-detemir	Completed	III	Insulin detemir: pharmacodynamics Effect on bodyweight In patients with type 2 diabetes mellitus previously treated with other basal insulins	Novo Nordisk
6 700039152	Insulin Pramlintide	Recruiting	II	Pramlintide + insulin: therapeutic use Diabetes mellitus Comparing multiple injection port and standard injections	Amylin Pharmaceuticals
7 700051303	Tagatose	Active, no longer recruiting	III	Tagatose: therapeutic use Type 2 diabetes mellitus Phase III proof-of-concept trial in patients undergoing diet and exercise: the NEET trial	Spherix
8 700041492	Diabetes-mellitus-vaccine Insulin Lansoprazole Sitagliptin	Active, no longer recruiting	II	Diabetes mellitus vaccine + lansoprazole + sitagliptin + insulin: therapeutic use Type 1 diabetes mellitus In patients with new onset disease	Diamyd Medical
9 700041224	Miglitol Voglibose	Completed	IV	Miglitol vs voglibose: therapeutic use Type 2 diabetes mellitus	

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Phase IV trial evaluating secretions of glucagon-like peptide-1 and gastric inhibitory polypeptide after a mixed meal

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10 700049274	Liraglutide NN-1250 NN-9068	Completed	I	NN 9068 vs NN 1250 vs liraglutide vs NN 1250 + liraglutide: adverse reactions Various toxicities In volunteers	Novo Nordisk
11 700015288	Rosiglitazone Valsartan	Completed	III	Rosiglitazone, valsartan: therapeutic use Effects on beta-cell function Phase III trial in patients with impaired glucose tolerance and/or impaired fasting glucose	GlaxoSmithKline, Novartis
12 700049069	Hyaluronidase Insulins	Active, no longer recruiting	I	Insulins +/- hyaluronidase: pharmacokinetics Postprandial pharmacokinetics and glucodynamics of approved insulin analogues and formulations containing hyaluronidase A phase I trial in volunteers utilising a euglycaemic clamp	Halozyme Therapeutics
13 700033573	Sitagliptin	Active, no longer recruiting	IV	Sitagliptin: pharmacodynamics Effects on the blood pressure Alone and in combination with enalapril in patients with metabolic syndrome	
14 700033143	Alogliptin Pioglitazone	Completed	III	Alogliptin +/- pioglitazone: pharmacodynamics Effects on postprandial lipids and lipoprotein parameters In patients with type 2 diabetes mellitus	Takeda Europe Research & Development Centre, Takeda Global Research and Development Center
15 700048667	Dapagliflozin	Active, no longer recruiting	II	Dapagliflozin: therapeutic use Type 2 diabetes mellitus In Japanese patients who have inadequate glycaemic control	AstraZeneca, Bristol- Myers Squibb
16 700028997	Insulin-glargine Insulin-neutral- protamine-lispro	Completed	III	Insulin glargine vs insulin neutral protamine lispro: therapeutic use Type 2 diabetes mellitus In patients receiving oral antihyperglycemics and exenatide	Eli Lilly
17 700043527	BI-10773 Metformin Sitagliptin	Active, no longer recruiting	II	BI-10773 +/- metformin, sitagliptin: adverse reactions Various toxicities, hypoglycaemia An open-label extension study in patients with type 2 diabetes mellitus	Boehringer Ingelheim

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18 700026139	Glucagon-like-peptide-1	Completed	II	Glucagon-like peptide 1: pharmacodynamics Effect on pancreatic alpha cell sensitivity In patients with type 2 diabetes mellitus	Novo Nordisk
19 700033445	Insulin-aspart Insulin-aspart/insulin-protamine-aspart Insulin-detemir	Completed	IV	Insulin aspart vs insulin aspart/insulin protamine aspart vs insulin detemir: therapeutic use Type 2 diabetes mellitus A phase IV observational study in patients who had been on human insulins	Novo Nordisk
20 700035752	Insulin-detemir	Completed	IV	Insulin detemir: adverse reactions Various toxicities In patients with type 2 diabetes mellitus	Novo Nordisk
21 700029075	Glimepiride Insulin-glargine	Active, no longer recruiting	IV	Insulin glargine vs glimepiride: therapeutic use Type 2 diabetes mellitus Effects on beta cell function and metabolic profile in patients failing metformin monotherapy	sanofi-aventis
22 700047377	Oxycodone/naloxone Pregabalin	Active, no longer recruiting	II	Pregabalin +/- oxycodone/naloxone: therapeutic use Neuropathic pain In patients suffering from moderate to severe pain due to diabetic polyneuropathy	Mundipharma GmbH, Mundipharma International
23 700023069	Sirolimus Sitagliptin Tacrolimus	Active, no longer recruiting	I	Sitagliptin + tacrolimus, sirolimus: pharmacokinetics Effects on tacrolimus and sirolimus pharmacokinetics In kidney transplant recipients with type 2 diabetes mellitus	
24 700050677	Glimepiride TAK-875	Recruiting	II	TAK 875 vs glimepiride: therapeutic use Type 2 diabetes mellitus In patients whose disease is inadequately controlled with diet and exercise or metformin	Takeda Global Research and Development Center
25 700038101	Exenatide	Completed	III	Exenatide: therapeutic use Type 2 diabetes mellitus In patients whose disease is not fully controlled by insulin glargine with or without oral antihyperglycaemic medications	Amylin Pharmaceuticals, Eli Lilly
26 700043407	GRT-6005 Morphine	Recruiting	II	GRT 6005 vs morphine: therapeutic use Neuropathic pain In patients with diabetic polyneuropathy	Grunenthal

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27 700032826	Insulin	Active, no longer recruiting	II	Insulin: adverse reactions Various toxicities Phase IIb trial of an oral capsule in patients with type 2 diabetes mellitus	Oramed Pharmaceuticals
28 700050427	JTT-654	Discontinued	II	JTT 654: therapeutic use Type 2 diabetes mellitus In patients treated with metformin or untreated patients	AKROS Pharma
29 700038141	Sitagliptin Sulfonylureas	Discontinued	IV	Sitagliptin vs sulfonylureas: adverse reactions Hypoglycaemia In patients with type 2 diabetes mellitus	
30 700050412	Insulin Metformin Vildagliptin	Recruiting	II	Insulin + metformin +/- vildagliptin: therapeutic use Type 2 diabetes mellitus	Novartis
31 700044246	Insulin	Recruiting	II/III	Insulin: therapeutic use Type 1 diabetes mellitus Tight blood glucose control in early disease	
32 700039554	Linagliptin	Active, no longer recruiting	III	Linagliptin: adverse reactions Various toxicities In type 2 diabetic patients with severe chronic renal impairment	Boehringer Ingelheim
33 700042867	Lixisenatide	Active, no longer recruiting	III	Lixisenatide: therapeutic use Type 2 diabetes mellitus In patients with disease insufficiently controlled with basal insulin with or without sulfonylurea	sanofi-aventis
34 700032756	Insulin-glargine	Completed	III	Insulin glargine: therapeutic use Diabetic ketoacidosis In children patients with early phase moderate to severe disease	
35 700038528	AZD-1656	Completed	I	AZD 1656: adverse reactions Various toxicities In patients with type 2 diabetes mellitus treated with metformin	AstraZeneca, AstraZeneca Pharmaceuticals
36 700048002	LX-4211	Completed	II	LX 4211: adverse reactions Various toxicities In patients with type 2 diabetes mellitus	Lexicon Pharmaceuticals
37 700046850	Colesevelam	Completed	II	Colesevelam: therapeutic use Hyperlipidaemia Cholesterol and glycaemic control in patients with type 1 diabetes mellitus	Daiichi Sankyo Inc

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38 700025020	Pioglitazone	Completed	II	Pioglitazone: pharmacodynamics Effect on biomarkers with proven links to future cardiovascular events Phase II trial in patients with peripheral arterial disease and type 2 diabetes mellitus	Wyeth
39 700014771	Pioglitazone	Completed	II	Pioglitazone: pharmacodynamics Effects on skeletal muscle and liver triglyceride content In patients with familial hyperlipidaemia	
40 700047680	Rosiglitazone	Completed	II	Rosiglitazone: therapeutic use Glucose intolerance In adolescents	
41 700020139	Sulodexide	Active, no longer recruiting	II	Sulodexide: pharmacodynamics Effects on systemic glycocalyx volume In patients with type 2 diabetes mellitus with or without microalbuminuria: the SUGAR trial	Alfa Wassermann SpA
42 700022664	Insulin-detemir Insulin-glargine Insulin-suspension-isophane	Completed	IV	Insulin detemir, insulin glargine, insulin suspension isophane: pharmacodynamics Effects on glucose production, lipolysis and proteolysis In men with type 2 diabetes mellitus: The BASIN study	Novo Nordisk
43 700035593	Insulin-detemir	Active, no longer recruiting	IV	Insulin detemir: adverse reactions Various toxicities In children and adolescents with type 1 diabetes mellitus	Novo Nordisk
44 700052781	Insulin-glargine LY-2605541	Recruiting	II	LY 2605541 vs insulin glargine: therapeutic use Type 1 diabetes mellitus	Eli Lilly
45 700051990	Insulin-glargine LY-2605541	Recruiting	II	LY 2605541 vs insulin glargine: therapeutic use Type 2 diabetes mellitus	Eli Lilly
46 700038757	Metformin	Recruiting	IV	Metformin: therapeutic use Type 2 diabetes mellitus In Chinese patients with newly diagnosed disease	Bristol-Myers Squibb
47 700048182	Metformin RO-5095932	Recruiting	I	RO 5095932 + metformin: therapeutic use Type 2 diabetes mellitus	Roche
48 700040791	RO-5027838 RO-5093151	Completed	II	RO-5093151 vs RO-5027838: therapeutic use Type 2 diabetes mellitus In patients on a stable dose of metformin	Roche

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49 700045988	Saxagliptin	Active, no longer recruiting	III	Saxagliptin: therapeutic use Type 2 diabetes mellitus In patients with inadequate glycaemic control with diet and exercise	AstraZeneca, Bristol-Myers Squibb
50 700040116	Taspoglutide	Completed	I	Taspoglutide: therapeutic use Type 2 diabetes mellitus Effect on first and second-phase insulin secretion	Roche
51 700051552	Alogliptin Metformin	Recruiting	III	Alogliptin vs metformin vs alogliptin + metformin: therapeutic use Type 2 diabetes mellitus	Takeda Global Research and Development Center
52 700043848	Exenatide	Active, no longer recruiting	II	Exenatide: therapeutic use Type 2 diabetes mellitus Delivered via the DUROS system: comparison with twice daily exenatide	Intarcia Therapeutics
53 700034209	Insulin-aspart Insulin-aspart/insulin-protamine-aspart Insulin-detemir	Recruiting	III	Insulin aspart vs insulin detemir vs insulin aspart/insulin protamine aspart: therapeutic use Type 2 diabetes mellitus	Novo Nordisk
54 700037247	Insulin-detemir Insulin-suspension-isophane	Completed	IV	Insulin detemir, insulin suspension isophane: pharmacodynamics Effect on renal handling of sodium, fluid retention and weight In patients with type 2 diabetes mellitus	
55 700039234	Glimepiride MK-0941	Completed	II	MK 0941 vs glimepiride: therapeutic use Type 2 diabetes mellitus In patients with inadequate glycemic control on metformin therapy	Merck & Co, Merck Frosst, Merck Sharp & Dohme
56 700034440	Nemonoxacin	Completed	II	Nemonoxacin: therapeutic use Diabetic foot ulcer, skin and soft tissue infections In patients with mild to moderate severity associated with gram-positive pathogens	TaiGen Biotechnology
57 700049722	PF-04971729	Completed	I	PF 04971729: adverse reactions Various toxicities In volunteers under fed and fasted conditions	Pfizer
58 700027738	Pioglitazone Sitagliptin Sitagliptin/metformin	Completed	III	Sitagliptin/metformin + sitagliptin vs pioglitazone: therapeutic use Type 2 diabetes mellitus	Merck & Co

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59 700035158	Atazanavir	Completed	II	Atazanavir: pharmacodynamics Effect on endothelial dysfunction, vascular inflammation and heme oxygenase activity In patients with type 2 diabetes mellitus	
60 700051987	Exenatide Liraglutide	Recruiting	III	Exenatide vs liraglutide: therapeutic use Type 2 diabetes mellitus In patients having inadequate glycaemic control treated with lifestyle modification and oral antidiabetic medications	Amylin Pharmaceuticals, Eli Lilly
61 700041695	Insulin-detemir	Active, no longer recruiting	III	Insulin detemir: therapeutic use Type 2 diabetes mellitus In patients using oral anti-diabetic drugs	Novo Nordisk
62 700012733	Insulin-glargine Insulin-neutral-protamine-lispro/insulin-lispro	Completed	IV	Insulin neutral protamine lispro/insulin lispro vs insulin glargine: therapeutic use Type 2 diabetes mellitus In combination with oral antihyperglycaemics: The DURABLE trial	Eli Lilly
63 700041707	Metformin Phentermine/topiramate Probenecid Sitagliptin	Completed	I	Phentermine/topiramate + metformin, sitagliptin, probenecid: pharmacokinetics Potential pharmacokinetic interactions In volunteers	VIVUS
64 700043733	Glipizide Metformin Pioglitazone Sitagliptin	Active, no longer recruiting	III	Pioglitazone + metformin + glipizide +/- sitagliptin: therapeutic use Type 2 diabetes mellitus In patients whose disease is inadequately controlled with metformin + pioglitazone	Merck & Co, Merck Frosst Canada - Schering Canada (JV), Merck Sharp & Dohme

For further information, please call +44 (0) 20 7981 0765 or send an e-mail to clientsupport@wolterskluwer.com.