

Clinical Trials History
Marin Endocrine Care and Research
11.18.2005

Sponsor	Protocol #	Indication	Description	Start Date	End Date	P.I.
Amylin	137-112	Type II DM	Effects of Pramlintide (AC137) on Glycemic Control as Determined by Glycated Hemoglobin	Oct 1995	Jan 2001	Gaudiani
Amylin	137-112E	Type II DM	Effects of Pramlintide (AC137) on Glycemic Control as Determined by Glycated Hemoglobin (Extension)	Jul 1998	Jan 2001	Gaudiani
Amylin	137-121	Type I DM	Effects of Pramlintide (AC137) on Glycemic Control as Determined by Glycated Hemoglobin	Mar 1998	Feb 2000	Bernstein
AstraZeneca	270	Type II DM- Oral	Efficacy & Safety of AZ 242 in Subjects with Type II Diabetes	Dec 2000	Feb 2003	Bernstein
AstraZeneca	Gallant 6	Type II DM- Oral	Study to Evaluate the Efficacy, Safety & Tolerability of Tesaglitazar Therapy	Aug 2004	(Jan 2006)	Bernstein
AstraZeneca	Gallex 6	Type II DM- Oral	Study to Evaluate the Efficacy, Safety & Tolerability of Tesaglitazar Therapy (Long Term Extension)	Jan 2005	(Jan 2008)	Bernstein
AstraZeneca	Gallant 9	Type II DM- Insulin	Study to Evaluate the Efficacy, Safety & Tolerability of Tesaglitazar Therapy	Aug 2004	(Jan 2006)	Bernstein
AstraZeneca	Gallex 9	Type II DM- Insulin	Study to Evaluate the Efficacy, Safety & Tolerability of Tesaglitazar Therapy (Long Term Extension)	Jan 2005	(Jan 2008)	Bernstein
AstraZeneca	G-Plus: Group 1	Type II DM- Follow-up	A Long-Term, Post treatment, Safety Follow-up, Multi-Centre Study in Patients with Type 2 Diabetes Mellitus from the GALLANT, GALLEX or ARMOR Studies (G-PLUS)	Sep 2005	(Sep 2007)	Bernstein
AstraZeneca	G-Plus: Group 2	Type II DM- Follow-up	A Long-Term, Post treatment, Safety Follow-up, Multi-Centre Study in Patients with Type 2 Diabetes Mellitus from the GALLANT, GALLEX or ARMOR Studies	Sep 2005	(Sep 2007)	Bernstein
Berlex	305140	Mild Hypertension/Post-menopausal symptoms	Oral Angeliq (HRT) versus placebo in the treatment of mild HTN in postmenopausal women	Feb 2002	Dec 2003	Bernstein
Berlex	306743	Hypertension/Post-menopausal symptoms	Oral Angeliq (HRT) versus placebo in the treatment of HTN in postmenopausal women	Apr 2004	Aug 2005	Bernstein

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Berlex	308960	Dysfunctional Uterine Bleeding	A Multicenter, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled, 7 Cycle Duration (196 days), Phase 3 Study of Oral Estradiol Valerate/Dienogest tablets for the Treatment of Dysfunctional Uterine Bleeding	Dec 2005	OPEN	Bernstein
Bristol-Myers Squibb	CV138-011	Type II DM	Safety & Efficacy of Metformin/Glyburide Therapy in Patients Who Have Failed Glycemic Control with Diet, Exercise and Max Doses of Sulfonylurea Therapy	Sep 1997	Jun 1999	Gaudiani
Bristol-Myers Squibb	CV138-019	Type II DM	Safety & Efficacy of Metformin/Glyburide Therapy As First Line Therapy	Dec 1997	Aug 2000	Gaudiani
Bristol-Myers Squibb	CV137-046	Type II DM	Study of the Antiproteinuric Effects of Ompatrilat and Amlodipine in Type II DM with HTN & Microalbuminuria or Overt Nephropathy	Feb 1999	Jun 1999	Bernstein
Bristol-Myers Squibb	CV138-043	Type II DM	Safety & Efficacy of Metformin/Glyburide Therapy in Patients Who Have Inadequate Glycemic Control on Max Dose Sulfonylurea Monotherapy	Mar 1999	Jun 1999	Gaudiani
Bristol-Myers Squibb	CV138-060	Type II DM	Safety & Efficacy of Metformin/Glyburide Therapy in Patients Who Have Inadequate Glycemic Control on Half-Max to Max Dose Sulfonylurea Monotherapy	Jun 2000	Jun 2001	Bernstein
Eli Lilly & Co.	F3Z-MC-IOCE(b)	Type II DM	Insulin Lispro in the Treatment of Patients with Type II DM after Oral Agent Failure	Feb 1995	Feb 1997	Gaudiani
Eli Lilly & Co.	H7U-MC-IDAS	Type I or II DM	A Pivotal, Open-Label, Parallel Study to Evaluate the Safety and Efficacy of Human Insulin Inhalation Powder (HIIP) Compared to Injectable Insulin in Patients With Diabetes and COPD or Asthma	Sep 2005	OPEN	Gaudiani

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Genentech, Inc.	F0695g	Type I DM	Study of the Combined Effects of Subcutaneously Administered Insulin and rhIGF-1 for the Treatment of Type I DM	Dec 1995	Aug 1996	Gaudiani
Genentech, Inc.	F0696g	Type II DM	Safety & Pharmacodynamic Effects of rhIGF-1 for the Treatment of Type II DM in Subjects Receiving Glyburide Treatment	Jul 1996	Dec 1997	Bernstein
Genentech, Inc.	F0708g	Type I DM	Study of the Combined Effects of Subcutaneously Administered Insulin and rhIGF-1 for the Treatment of Type I DM (Phase III)	Apr 1997	Dec 1998	Gaudiani
GlaxoSmithKline	(ADOPT) 49653/048	Type II DM- Drug-Naïve	Comparative Study: Rosiglitazone compared to Metformin or Glyburide	Jan 2000	(Jun 2006)	Bernstein
Hoffman Laroche	BM14330	Diabetic Neuropathy	Acetyl-L-Carnatine & Neuropathy	May 1994	Dec 1995	Bernstein
Hoffman Laroche	BM15006	Diabetic Neuropathy	Acetyl-L-Carnatine & Neuropathy	May 1994	Dec 1995	Bernstein
Hoffman Laroche	WM14783	Diabetic Foot Ulcer	Acetyl-L-Carnatine & Foot Ulcer	May 1994	Dec 1995	Bernstein
IDD	676/US/2-01	Diabetic Neuropathy	Safety & Pharmacokinetic Study of IDD-676 Administered for up to 26 Weeks	Jan 2001	Mar 2003	Bernstein
INSMED, Inc.	INS1-PO-29	Polycystic Ovary Syndrome (PCOS)	Research on the Use of D-chiro-inositol for the Treatment of PCOS	Jun 2001	Jun 2002	Bernstein
Knoll	SB118-22	Obesity	Long-Term Efficacy & Safety of meridia (sibutramine hydrochloride) in Obese Patients	Jan 1999	Sep 2003	Bernstein

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Lifescan	658-95-C01	Glucose Monitoring	Accuracy & User Acceptance of the SureStep, the Accu-Chek Easy and the Accu-Chek ADVANTAGE	Aug 1995	Dec 1995	Bernstein
Novo Nordisk	NN305-1337	Type II DM	Safety & Efficacy of Combination Therapy of Metformin with NN304 or NPH	Apr 2001	Feb 2003	Bernstein
Merck	147-00	Type II DM/Nephropathy	Study to Evaluate the Renal Protective Effects of Losartan	Jun 1996	Jun 1998	Gaudiani
Merck	187-00	Type II DM	Efficacy & Safety of Treatment with Simvastatin in Thiazolidinedione Treated Type II DM Patients	Jul 2000	Jul 2002	Gaudiani
Merck	006-00	Type II DM	Study to Evaluate the Glucose-Lowering Efficacy, Lipid-Lowering Efficacy, Lipid-Altering Efficacy, Safety & Tolerability of L-410198	Sep 2000	Sep 2002	Gaudiani
Merck	012-00	Type II DM	Safety & Tolerability of L-410198 (IIb)	Feb 2002	May 2004	Gaudiani
Merck	021-00	Type II DM	Efficacy & Safety of Simvastatin Monotherapy Compared with Simvastatin Plus Ezetimibe (SCH 58235) in Type II DM Treated with TZDs	Feb 2002	Apr 2003	Gaudiani
Merck	012-10	Type II DM	Safety & Tolerability of L-410198 (IIb)	Mar 2002	May 2004	Gaudiani
Merck	012-11	Type II DM	Safety & Tolerability of L-410198 (III)	Dec 2002	May 2004	Gaudiani
Merck	025-00	Type II DM	Safety & Efficacy of the Addition of MK-0767 to Patients with Type II DM with Inadequate Glycemic Control on Combined Metformin & Sulfonylurea Therapy	Feb 2003	May 2004	Gaudiani
Merck	030-00	Type II DM	Safety & Efficacy of the Addition of MK-0767 to Patients with Type II DM on Insulin Therapy	Apr 2003	May 2004	Gaudiani
Merck	005 L-000414380	Type II DM/Metabolic Syndrome	Efficacy & Safety of L-000414380 in treatment of DM and Metabolic Syndrome	Jul 2004	April 2005	Bernstein
Merck	020 MK-0431	Type II DM	Efficacy & Safety of the addition of MK-0431 compared with sulfonylurea therapy + metformin	May 2004	(Dec 2006)	Gaudiani
Merck	011	Hyperlipidemia	Tolerability & Effects of MK-0524 on Lipids	Jun 2004	Mar 2005	Gaudiani

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Merck	011-10	Hyperlipidemia	Tolerability & Effects of MK-0524 on Lipids (Extension)	Nov 2004	(Nov 2006)	Gaudiani
Merck	023	Type II DM	Study MK-0431 in Patients Who Have Inadequate Glycemic Control	Aug 2004	(Apr 2006)	Gaudiani
Merck	035	Type II DM	Safety & Efficacy of MK-0431 in Patients Who Have Inadequate Glycemic Control on Glimerpiride Alone or in Combination With Metformin	Mar 2005	(Sep 2006)	Bernstein
Merck	065	Type II DM	Efficacy & Tolerability of MK-0478 Co-administered with Insulin	June 2005	Terminated	Bernstein
Merck	020 Obesity	Obesity	Efficacy, Safety & Tolerability of L-000899055 in Obese Patients	Jul 2005	(Apr 2007)	Gaudiani
Parke-Davis	991-068-013	Type II DM	Troglitazone (CI-991) Type II DM Patients Requiring Insulin	Sep 1995	Mar 1999	Bernstein
Parke-Davis	991-101-003	Polycystic Ovary Syndrome (PCOS)	Safety & Efficacy of Troglitazone (CI-991) in PCOS	Jul 1997	Mar 1999	Bernstein
Parke-Davis	991-148-002	Type II DM	Troglitazone (CI-991) plus Metformin in Early-Stage Type II DM Patients	Mar 1999	Mar 2001	Bernstein
Parke-Davis	991-241-002	Type II DM	Troglitazone (CI-991) plus Metformin in Type II DM Patients Not Optimally Controlled on Metformin	Sep 1999	Sep 2001	Bernstein
Parke-Davis	1027-004-014	Low HDL-C	Efficacy & Safety of CI-1027	May 2000	May 2002	Bernstein
Pfizer	981-071-028 (orig. Parke-Davis)	Type I DM	4-Year Study of Atorvastatin as Secondary Prevention of CHD	Jul 1996	Dec 2000	Bernstein
Pfizer	A2631014	Type II DM	Study of CP-368,296 (Ingliforib) on Glucose Control (II)	Feb 2001	Feb 2003	Bernstein
Pfizer	A2171029	Type II DM	Efficacy & Safety of Exubera Compared with Subcutaneous Insulin	Mar 2002	(Mar 2006)	Bernstein

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Pfizer	A2171029X	Type II DM	Efficacy and Safety of Exubera Compared with Subcutaneous Human Insulin Therapy in Adult Subjects with Type II DM: A Two-Year, Outpatient, Open Label, Parallel Group Comparative Trial	May 2005	(Jun 2007)	Bernstein
Pfizer	A1481207	Type II DM	Sildenafil for Glycemic Control in Patients with Type II DM With & Without Metformin	Oct 2003	Aug 2004	Bernstein
Pfizer	A5901018	Hyperlipidemia	Efficacy, Safety & Tolerability of Fixed Combination Torcetrapib/Atorvastatin	Apr 2004	Closed	Gaudiani
Pfizer	A2171028	Type I or II DM/Chronic Asthma	Efficacy & Safety of Exubera Compared with Subcutaneous Insulin	Oct 2004	OPEN	Gaudiani
Pfizer	A2171030	Type I or II DM/COPD	Efficacy & Safety of Exubera Compared with Subcutaneous Insulin	Oct 2004	OPEN	Gaudiani
Takeda-Quintiles	AO-128/PNFP-001	Type II DM	Study of Voglibose (AO-128) in Type II DM Patients	Dec 1996	Dec 1998	Bernstein
Takeda-Quintiles	AO-128/PNFP-006	Type II DM	Study of Voglibose (AO-128) in Type II DM Patients (Extension)	Dec 1996	Dec 1998	Bernstein
Wyeth-Ayerst	81-084-US	Retinopathy	Tolrestat Retinopathy	Apr 1990	Oct 1995	Bernstein
Wyeth-Ayerst	81-085-US	Retinopathy	Tolrestat Retinopathy	Jan 1993	Oct 1995	Bernstein
Wyeth-Ayerst	84-196-US	Retinopathy	Tolrestat Retinopathy	Jan 1990	Oct 1995	Bernstein
Wyeth-Ayerst	84-197-US	Retinopathy	Tolrestat Retinopathy	Jan 1991	Oct 1995	Bernstein

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Wyeth-Ayerst	709A-300-US	Insulin-dependent	Safety & Efficacy of oral Tolrestat compared with placebo for the prevention of Nephropathy	Jul 1991	Jul 1996	Bernstein
Wyeth-Ayerst	709A-304-US	Insulin-dependent	Safety & Efficacy of oral Tolrestat compared with placebo for the prevention of Neuropathy	Jul 1991	Jul 1996	Bernstein
Wyeth-Ayerst	709A-308-US	Insulin-dependent	Safety & Efficacy of oral Tolrestat compared with placebo for the prevention of Neuropathy (EXTENSION)	Jul 1991	Jul 1996	Bernstein
Wyeth-Ayerst	0600B3-215-US	Diabetic Neuropathy	Venlafaxine Extended Release Capsules for the Treatment of Chronic Pain Associated with Diabetic Neuropathy	Feb 1993	May 1999	Bernstein
Wyeth-Ayerst	0600B3-215-US	Diabetic Neuropathy	Venlafaxine Extended Release Capsules for the Treatment of Chronic Pain Associated with Diabetic Neuropathy (Extension)	Feb 1995	May 1999	Bernstein