PEGASUS-TIMI (2010-2015) A phase 3 randomized, double-blind, placebo controlled, parallel group, multinational trial, to assess the prevention of thrombotic events with ticagrelor compared to placebo on a background of acetyl salicylic acid (ASA) therapy in patients with history of myocardial infarction. Primary outcome measures was any event after randomization from the composite of cardiovascular death, non-fatal MI, or non-fatal stroke. Industry sponsored.

COSMIC-HF Trial (2013-2015) A phase 2 double-blind, randomized, placebo-controlled, multicenter, dose escalation study to select and evaluate an oral modified release formulation of omecamtiv mecarbil in subjects with HF and left ventricular systolic dysfunction. The primary objectives of this study was (i) to select an oral modified release (MR) formulation and dose of omecamtiv mecarbil for chronic twice daily (BID) dosing in subjects with HF and left ventricular systolic dysfunction and (ii) to characterize its pharmacokinetics (PK) after 12 weeks of treatment. Industry sponsored.

LMS 002 (2011-2014) A phase 3 multicenter, double-blind, placebo-controlled randomized discontinuation study followed by an open-label extension period to evaluate the efficacy and safety of amifampridine phosphate (3,4-diaminopyridine phosphate) in patients with Lambert-Eaton Myasthenic Syndrome (LEMS). Primary outcome measure was change from baseline Quantitative Myasthenia Gravis (QMG) at 14 days. Industry sponsored.

Lurasidone HCl (2008-2014) Select trials in a phase 3 clinical development will include multiple independent trials of SM-13496. One trial is randomized, placebo and-active comparator controlled, clinical trial to study the safety and efficacy of two doses of lurasidone HCl in acutely psychotic patients with schizophrenia. The primary outcome measure was change in total PANSS score from baseline to the end of the double blind treatment period.

ATOMIC-AHF (2011-2013) A phase 2, double blind, placebo controlled, multicenter study to evaluate the safety and efficacy of IV infusion treatment with omecamtiv mecarbil in subject with left ventricular systolic dysfunction hospitalized for acute heart failure. The primary objective of the study is to evaluate the effect of 48 hours of intravenous (IV) omecamtiv mecarbil compared with placebo on dyspnea in subjects with left ventricular systolic dysfunction hospitalized for acute heart failure. Industry sponsored.


**REDHF Trial** (2006 -2013) A phase 3, double blind, randomized, placebo controlled, multicenter study to assess the efficacy and safety of darbepoetin alfa treatment on mortality and morbidity in heart failure (HF) subjects with symptomatic left ventricular systolic dysfunction and anemia. Primary endpoint was time to death from any cause or first hospital admission for worsening HF, whichever occurred first. Industry sponsored


**AMG 785** (2009-2012) A phase 2 clinical trial studied the safety and efficacy of AMG 785, an investigational bone building agent, in the treatment of postmenopausal women with low bone mineral density. Different doses and dosing frequencies of AMG 785 were compared to placebo in a double-blind fashion. The primary outcome was percent change from baseline in lumbar spine bone mineral density. Industry sponsored.


**A8851009** (2007-2011) A phase 3 prospective, randomized trial comparing the efficacy of anidulafungin and voriconazole in combination to that of voriconazole alone when used for primary therapy of proven or probable invasive aspergillosis (IA). The primary endpoint was all cause mortality, measured 6 weeks after IA initiation of study drug in subjects with proven or probable IA.


**MGA031** (2006- 2011) A phase 2/3, randomized, double blind, multicenter, multinational, 4-arm, controlled, dose ranging study to evaluate efficacy and safety of MGA031, a humanized, FcR non-binding, anti-CD3 monoclonal antibody, in children and adults with recent-onset type 1 diabetes mellitus. Industry sponsored.

**TREAT (2004-2010)** A randomized, double blind, multicenter study to assess the effect of anemia therapy with darbepoetin alpha on the composite event comprising all cause mortality and cardiovascular (CV) events in subjects with both chronic kidney disease (CKD) and Type 2 diabetes mellitus (DM). Industry sponsored.


**PLATO (2006-2009)** A randomized, double blind, parallel group, international, multicenter study comparing the efficacy and safety of AZD6140 90mg twice daily with clopidogrel 75mg once daily in the prevention of fatal and nonfatal cardiovascular events in patients with non-ST or ST elevation ACS. Industry sponsored.


**CP-945,598 Obesity (2007-2009)** A phase 3 clinical development program to evaluate the efficacy and safety of CP-945,598 in the treatment of obese subjects. The program was terminated on November 3, 2008 due to changing regulatory perspectives on the risk/benefit profile of the drug class and likely new regulatory requirements for approval. No safety issues were involved in the termination decision. Industry sponsored.

**RWJ333369 (2006-2008)** A randomized, double blind, placebo controlled, dose-titration study to determine safety, tolerability and preliminary efficacy of RWJ-333369 as adjunctive therapy in subjects with treatment-resistant partial seizures or primarily generalized tonic-clonic seizures. Industry sponsored.


**I-PRESERVE (2002-2008)** A randomized, double blind, multicenter study comparing Irbesartan, an angiotensin II receptor antagonist, verus placebo in subjects with advanced heart failure and with preserved systolic function. Primary endpoint is all cause mortality or cardiovascular morbidity. Industry sponsored.


**CORONA (2004-2007)** A phase 3, randomized, double blind, placebo controlled study with rosvastatin in subjects with chronic symptomatic systolic heart failure. Comparison of rosvastatin, along with all other medications prescribed, versus placebo. Combined primary endpoint was cardiovascular death or non-fatal MI or non-fatal stroke. Industry sponsored. Results presented at the November 2007 American Heart Association meeting.


**COX 2 INHIBITOR PROGRAM (2005-2007)** This clinical development program for a dual-acting COX2 inhibitor was expected to include approximately 40,000 subjects in 36 phase 3 multicenter, randomized, placebo-and active comparator-controlled, studies in multiple indications including osteoarthritis, rheumatoid arthritis, chronic low back pain, neuropathic pain, visceral pain and acute pain. The program was terminated early due to insufficient efficacy in initial studies. Industry sponsored.

**EVEREST (2003-2007)** A randomized, multicenter, double blind study comparing tolvaptan, a vasopressin receptor antagonist, in conjunction with optimal current therapy on the time to all-cause mortality, versus placebo in subjects with worsening congestive heart failure. Primary outcomes are all cause mortality, cardiovascular mortality or CHF morbidity and global clinical status. Industry sponsored.


**ARIES (2004-2006)** Two phase 3, randomized, double blind, placebo controlled, multicenter, efficacy studies of ambrisentan in subjects with pulmonary arterial hypertension. Primary endpoint was the change from baseline in the six-minute walk distance evaluated after 12 weeks of therapy. Industry sponsored.


**ILLUMINATE (2004-2006)** A multi-center, double blind, randomized, parallel group evaluation of the fixed combination torcetrapib/atorvastatin, administered orally, once daily, compared with
atorvastatin alone, on the occurrence of major cardiovascular events in subjects with coronary heart disease or risk equivalents. Industry sponsored. Results presented at the November 2007 American Heart Association meeting.


**ADOPT** (2000-2006) A randomized, double blind clinical trial to compare the durability of glucose lowering and preservation of pancreatic beta cell function of rosiglitazone monotherapy compared to metformin or glyburide/glibenclamide in subjects with drug-naïve, recently diagnosed Type 2 diabetes mellitus. Primary outcome was monotherapy failure. Industry sponsored.


**CSMS 802 & 804** (1999-2006) A randomized, double blind study on the efficacy and safety of Sandostatin LAR in the therapy of subjects with moderately severe or severe non-proliferative diabetic retinopathy (NPDR) or low risk proliferative diabetic retinopathy (PDR). Primary outcome was progression of retinopathy. Industry sponsored.

**PAA20001** (2004-2005) A multicenter, three staged, randomized, parallel group, double blind, fenofibrate and placebo controlled dose-response evaluation of the safety, tolerability and effects on plasma high-density lipoprotein cholesterol and triglycerides of eight weeks treatment with daily doses in otherwise healthy subjects with low HDLc, mildly to moderately elevated triglycerides and normal low-density lipoprotein cholesterol. Study drug was a peroxisome proliferator-activated receptor (alpha) agonist. Industry sponsored.


**AGT** (2003-2005) A randomized, double blind, placebo controlled clinical trial to evaluate the efficacy and safety of Ad5FGF. Primary outcome was change from baseline in treadmill exercise duration at 12 weeks following treatment. Industry sponsored.

**APC** (2001-2005) A randomized, double blind, multicenter, placebo controlled study to evaluate the efficacy and safety of celecoxib in reducing the percentage of adenoma subjects with newly detected adenomas at surveillance colonoscopy. Comparison of two doses of celecoxib, a COX-2 inhibitor, versus placebo. Primary outcome was the occurrence of new adenomatous
polyps. NCI and industry sponsored. Results presented at April 2006 American Association for Cancer Research Annual Meeting.


**VERITAS** (2003-2004) A randomized, multicenter, double blind, placebo controlled, parallel group study to assess the efficacy, safety, and tolerability of tezosentan in subjects with acute heart failure. Primary endpoint was the incidence of death or worsening heart failure at 7 days following study drug initiation. Industry sponsored.


**TNT** (2000-2004) A randomized, double blind, parallel group study of the effect of LDL-Cholesterol lowering beyond currently recommended minimum targets on coronary heart disease (CHD) recurrence in subjects with pre-existing CHD. Primary outcome was major CHD event defined as either CHD death or non-fatal myocardial infarction. Industry sponsored. Results presented at March 2005 American College of Cardiology Late-Breaking Trials.


**SPORTIF 3 and V** (2000-2004) A randomized, multicenter, multinational, double blind, parallel group study in subjects with chronic non-valvular atrial fibrillation. Primary outcome was stroke and systemic embolic events. Industry sponsored. Results from SPORTIF 3 were presented at April 2003 American College of Cardiology Late-Breaking Trials.


COMPANION (1999-2002) An open-label, prospective, multicenter, randomized clinical trial. Comparison of optimal drug treatment versus optimal drug treatment with biventricular pacing versus optimal drug treatment with biventricular pacing and defibrillation. Primary endpoint was all-cause mortality/all-cause hospitalization. Results presented at March 2003 American College of Cardiology Late-Breaking Trials and September 2003 Heart Failure Society of America Late-Breaking Trials.


ENABLE (1999-2001) A randomized, double blind, placebo controlled study to assess the effects of Ro 47-0203 (Bosentan) on the morbidity and mortality of subjects with chronic heart failure. Primary endpoints were (1) all-cause mortality/hospitalization for heart failure and (2) clinical status at nine months. Industry sponsored. Results presented at March 2002 American College of Cardiology Late-Breaking Trials.


VIETNAM TAMOXIFEN STUDY (1993-2001) A randomized clinical trial of adjuvant oophorectomy and tamoxifen in premenopausal women subjects with operable breast cancer from Vietnam and China. Primary outcomes were overall survival and recurrence free survival. Supported by grants from the US NIH CA 64339, University of Wisconsin Clinical Cancer Center, and by the International Breast Cancer Research foundation, Madison, Wisconsin, USA.


**EXCITE** (1997-1999) A randomized, double blind, parallel design, placebo controlled, international, multicenter study designed to compare the efficacy and safety of xemilofiban to placebo when administered to subjects prior to and for up to six months after percutaneous revascularization procedures. Primary outcome was occurrence of death, MI, or urgent revascularization at 6 months. Industry sponsored. Results presented at March 1999 American College of Cardiology Meeting.


**MERIT** (1997-1999) A randomized double blind, placebo controlled survival study with metoprolol CR/XL in subjects with decreased ejection fraction and symptoms of heart failure. Primary outcome was mortality with composite of all-cause mortality and all-cause hospitalization as a secondary endpoint. Industry sponsored. Results presented at March 1999 American College of Cardiology Meeting and at August 1999 European College of Cardiology Meeting.


**REACH** (1997-1998) A double blind, randomized, placebo controlled study to assess the effects of Ro 470203 (Bosentan) on the morbidity and mortality of subjects with chronic heart failure. Primary endpoint was change in clinical status. Industry sponsored. Results presented at 1998 American Heart Association Meeting.


**AB-02** (1995-1998) A randomized, double blind clinical trial comparing Adenosin, an additive to cardioplegic solutions, versus placebo in subjects with depressed ventricular function undergoing coronary artery bypass graft surgery. Primary outcome was the amount of 1) dopamine and 2) inotropic support used during the first seven postoperative days. Industry sponsored.


**ACTS** (1992-1995) A randomized, double blind study comparing rHCNTF, a neurotrophic growth factor, in two doses versus placebo in subjects with amyotrophic lateral sclerosis. Primary outcome was rate of change from baseline in isometric muscle strength to nine months. Industry sponsored. SDAC served as the data management center as well as the analysis center. Results presented at May 1995 American Academy of Neurology Meeting.


**PRAISE** (1992-1994) A randomized, double blind study comparing Amlodipine, a calcium channel blocker, versus placebo in subjects with severe heart failure (Class 3b and 4). Primary outcomes were all-cause mortality and hospitalization for major cardiovascular events. Industry sponsored.


PROMISE (1989-1990) A randomized, double blind study comparing Milrinone, a phosphodiesterase inhibitor, versus placebo in subjects with severe chronic heart failure (Class 3 and 4). Primary outcome was all-cause mortality. Industry sponsored.


Wisconsin Tamoxifen Study (1986-1988) A randomized double blind study comparing Tamoxifen versus placebo in post-menopausal women under the age of 65 with node negative breast cancer. Primary outcomes were toxicity, bone density, and lipid and lipoprotein changes. Sponsored by American Cancer Society and industry.
